EMULATING COMMERCIAL, PRIVATE-SECTOR VALUE-CHAINS TO IMPROVE ACCESS TO ORS AND ZINC IN RURAL ZAMBIA: EVALUATION OF THE COLALIFE TRIAL

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Abstract

Globally, diarrhea remains a leading cause of avoidable morbidity and mortality in children under 5. The most pressing challenges and recommendations for the reduction of childhood diarrhea today are consistent with those described over the past decade, pointing to a need for innovation. Key challenges include insufficient access, production, distribution and promotion of essential commodities like ORS and zinc, the globally recommended treatments. Market-based solutions that engage the private sector and simultaneously stimulate both supply and demand of these commodities have been recommended as a way of increasing coverage, and ultimately reducing mortality.

The ColaLife project aimed to emulate the commercial, private-sector value chains of fast moving consumer goods (FMCGs), like Coca-Cola, and apply similar principles to the development and introduction of an innovative diarrhea treatment kit called the Kit Yamoyo®. This dissertation explores key elements related to the establishment of an end-to-end value-chain for this new product in Zambia. It includes 1) analysis of the overall impact of the approach on uptake of ORS and zinc, 2) determining the effect of applying human-centered design to global health product innovation, and 3) a detailed description of commercial general stores to inform their potential as informal, community-level providers of public health commodities.

The main data sources include cross-sectional, rural household surveys conducted in August of 2012 (baseline) and August of 2013 (endline), as well as retailer surveys conducted in March of 2013 (midline) and August of 2013 (endline). Questionnaires were administered to 2458 and 2477 caregivers of

children under 5, across 4 rural districts of Zambia, at baseline and endline, respectively. Two districts (Kalomo and Katete) served as intervention districts, while the other two (Monze and Petauke) served as matched comparators. Paper #1 uses a generalized linear model (GLM) with Poisson distribution to calculate the adjusted relative risk of combination therapy use in intervention districts vs. comparator districts at endline. Secondary analysis uses difference-in-differences estimation to compare ORS use (with or without zinc) in the intervention and comparison districts, before and after market-shaping activities. Paper #2 compares ORS use in children under 5 with diarrhea who either used Kit Yamoyo or standard one-liter sachets of ORS from rural health centers. Data drawn from the endline survey is analyzed using logistic regression and calculates the odds of correct preparation of ORS (i.e. concentration) in kit-users vs. non-users. Secondary analysis examines to what extent preparation of ORS in the correct concentration, or other factors, are associated with a change in the odds of perceiving ORS as effective. Paper #3 is predominantly descriptive in nature. It uses retailer survey data from 180 interviews of general, community-level retailers across the 4 study districts, who commonly sell FMCGs, to explore the potential of using them as outlets for provision of basic public health products like ORS and zinc. Findings are grouped under key themes including: infrastructure, staffing, ownership and operations, purchasing patterns, product preferences, and level of engagement with an intervention to expand coverage of a newly introduced diarrhea treatment kit.

Within the span of one-year, use of ORS and zinc combination therapy in children under 5 years of age with diarrhea, increased from less than 1% at baseline

to 46.6% across the intervention districts, while no change was seen in comparator districts. Difference-in-differences analysis comparing ORS use (with or without zinc) in the intervention and comparator districts, before and after market-shaping activities, found that ORS use increased significantly across intervention districts from 59.8% to 76.4%, while usage across comparators decreased non-significantly from 66.4% to 58.2%. In the intervention districts, there was a significant shift in point of access, from the public (originally the only point of access in rural Zambia) to the private sector, with introduction of the kit through community-level retailers.

Rational use of ORS, defined as preparing and consuming ORS in the correct concentration, differed significantly between Kit Yamoyo users and users of standard one-liter ORS sachets. Kit Yamoyo, having been developed through a human-centered design (HCD) process resulting in smaller (200mL) ORS sachets and provision of a measurement vessel in the form of the kit's packaging, increased the odds of correctly preparing ORS by 10.93 times as compared to one-liter sachet users. Kit users prepared ORS in the correct concentration 93% of the time, while users of standard one-litre sachets prepared it in the correct concentration only 60% of the time. Secondary analysis found that correct preparation of ORS significantly increased the odds of perceiving ORS as effective, along with having heard a message related to ORS in the previous 3 months. Caregiver's age was also significantly associated with perception of ORS, with the odss of perceiving ORS as effective decreasing with age.

In rural Zambia there exists a largely untapped potential to leverage community-level, general store retailers, who commonly sell fast-moving consumer goods (FMCGs)

like soap, snacks and beverages, to expand access to select public health products (PHPs) like ORS and zinc. On average, these types of shops are open longer than rural health facilities. Retailers typically purchase goods multiple times per month, from multiple wholesalers, providing increased opportunity for supply when compared to the public sector. With 87% of rural general store retailers having been asked for advice related to diarrhea treatment, they are well placed to help address market demand. With an average gross margin of 29% across other FMCGs commonly sold by these retailers, margins on PHPs can meet the profit needs of the retailers by following suit and remain affordable for the majority of people. The leading motivational factors indicated by general retailers for carrying a PHP were helping children and their community followed by profit. Following the introduction of the Kit Yamoyo, 76% of retailers were found to have it in stock on the day of visit, improving upon stock rates at rural health facilities.

Implementation of a value-chain approach for over-the-counter public health products, like a diarrhea treatment kit, can significantly improve coverage at the community level. Adopting a human-centered design approach in the development of PHPs and other public health interventions allows for greater consideration of demand-related factors of access, such as acceptability, and can lead to improved product innovation, appropriate utilization and perceived efficacy, as well as a strengthened value-chain.

Evidence that standard 1-liter ORS sachets are often being prepared incorrectly and administered without zinc, has important implications for design and optimal product presentation for diarrhea treatment. In addition, it implies that one of the standard global indicators used to measure progress in the treatment of diarrhea globally – coverage –

may not be a completely accurate way of measuring progress. Measuring *effective/rational* use of treatments is vital when considering the details of implementation. Co-packaging of ORS with zinc and soap, smaller sachets of ORS (i.e. 200mL), packaging that doubles as a measurement vessel, and enabling access through community-level general retailers (which presumes ORS and zinc have over-the-counter status) are features of an effective product and value-chain for diarrhea treatment that can help enable greater access at the household level.

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List of Acronyms

DTK Diarrhea Treatment Kit
BoP Bottom of the Pyramid / Base of the Pyramid
iCCM Integrated Community Case Management
CE Cost-Effectiveness
CHW Community Health Worker
CIDRZ Center for Infectious Disease Research Zambia
CHMI Center for Health Market Innovations
COTZ ColaLife Operational Trial Zambia
DGAP Diarrhea Global Action Plan
DHMT District Health Management Team
DMS District Medical Store
EM Essential Medicines
EMLIP Essential Medicines Logistics Improvement Programme (JSI/USAID)
FMCG Fast moving consumer goods
GCC Grand Challenges Canada
GNI Gross National Income
GRZ Government of the Republic of Zambia
HC Health Center
HCD Human-Centered Design
IEC Information, Education and Communication
IHME Institute of Health Metrics and Evaluation
IMCI Integrated Management of Childhood Illnesses
IP Intellectual Property
KYTS Kit Yamoyo Transition to Scale (Phase II project)
KZF Keepers Zambia Foundation
LMIC Low- and middle-income countries
M&E Monitoring and Evaluation
M&L Monitoring & Learning
MCDMCH Ministry of Community Development Mother & Child Health
MNCH Maternal and Child Health
MoH Ministry of Health
MSL Medical Stores Ltd
MSRP Manufacturer's suggested retail price
MTZL Mobile Transactions Zambia Ltd, now trading as Zoona
ORS Oral Rehydration Salts
ORSZ Oral Rehydration Salts and Zinc combination therapy
ORT Oral Rehydration Therapy
OTC Over-the-Counter
PM Project Management
PPP Purchasing Power Parity
PRA Pharmaceutical Regulatory Authority
RRP Recommended Retail Price
SSS Sugar-Salt Solution
SUN Scaling Up Nutrition program
U5 Under 5 (years old)
WASH Water, Sanitation and Hygiene
WHO World Health Organization
UNICEF United Nations Children's Fund
ZAMRA Zambian Medicines Regulatory Authority

Chapter 1 Background

1.1. Introduction

The 2013 Lancet Series on Childhood Diarrhea and Pneumonia noted that the most pressing challenges in the reduction of childhood deaths from diarrhea included insufficient access, production, distribution and promotion of key commodities, and that there was a need to strengthen supply systems that deliver essential commodities like Oral Rehydration Salts (ORS) and zinc (Gill *et al.,* 2013). These challenges are consistent with those identified over the past decade (Bryce *et al.,* 2005; Bhutta *et al.,* 2010; Fischer-Walker *et al*., 2009), leading to increased calls for innovation. Market-based solutions that engage the private sector and simultaneously stimulate both supply and demand of these essential commodities have been recommended as a way of overcoming such barriers.

1.1.1. The ColaLife Project

The ColaLife project attempted to address these key gaps by piloting an innovative global health delivery model in Zambia. With the intention of improving access and effective use of ORS and zinc at the household level in rural Zambia, it applied a health systems lens to address gaps. More specifically, the approach involved emulating the value-chains of private sector, fast-moving consumer goods (FMCGs), like Coca-Cola, and applying similar principles to a newly developed diarrhea treatment kit (Figure 1.1). The treatment kit, called Kit Yamoyo ("Kit of Life" in multiple local languages) was developed in conjunction with the intended

end-user (i.e. caregivers of children under 5) using a human-centered design approach. Designed for home use, the kit was innovative in that it:

- Co-packaged low-osmolarity, orange flavored ORS (4 sachets) and zinc (1 blister pack of ten dispersible, pediatric formulated tablets) (ORSZ);
- Contained smaller [than the global standard] sachets of ORS (200mL vs. 1L) more suitable for home use;
- Included a small bar of hand-washing soap to tie in the message of prevention and add to the kit's attractiveness;
- Included packaging that doubled as a measurement vessel to facilitate correct preparation of the ORS;
- Integrated a graphical instructional pamphlet that doubled as the branding for the product; and
- Focused on continual localization of the manufacturing of the product

An end-to-end value-chain for the product was then established, which included tapping into the same, existing, private sector distribution channels as other FMCGs. These distribution channels are made up of district level wholesalers, as well as the community-level, general retailers who regularly procure products from them and operate shops across "the last mile". These general stores (sometimes called grocery shops) make up the majority of private sector outlets in rural Zambia, with retailers regularly procuring products from district level wholesalers via bicycle, motorcycle, car, lorry, and a variety of other means. Each player in the product's value-chain stands to make profit, which plays a role in driving delivery and sustainability of that product at the community-level. The model is meant to complement (not replace) the diarrhea services provided through public health centers (including their affiliated community health workers), which tend to be the only other points of access for ORS and Zinc, providing choice and an additional option for caregivers at the community level.

1.1.2. Organization of the Document

This dissertation aimed to evaluate key aspects of this "ColaLife model", drawing on data from household and retailer surveys conducted across 4 rural districts. It starts by providing information related to key background concepts considered in the development and evaluation of the model (Section 1.3), including the rationale for the study and the approach in Zambia. Additional relevant literature review is provided within the Introductions of each research paper (Chapters 2, 3 and 4). The aims and objectives (Section 1.4) of the project and the research, more specifically, are then presented, including the key research questions that form the basis of this dissertation. Section 1.5 then presents the relevant conceptual framework and overall methodology used for the larger project from which the specific dissertation papers are derived. Chapter 2 provides an analysis of the overall impact of the value-chain approach on uptake of ORS and zinc combination therapy, as well as on ORS (with or without zinc) (Paper #1). Chapter 3 explores the role of human-centered design in global health product innovation. More specifically, it examines the effect of applying HCD in the development of a diarrhea treatment kit and its resulting effect on rational use, and in turn, perceived effectiveness of ORS (Paper #2). Chapter 4 provides a detailed description of rural, community-level, general stores in Zambia. It explores the potential of leveraging these types of retail outlets to expand coverage of basic public health products that can be easily administered at the household level (Paper #3). Finally, Chapter 5 concludes with a discussion of the potential policy implications of the findings and provides a set of recommendations. The affiliated tables and figures appear at the end of each respective chapter. Selected data collection tools and additional

information/analyses associated with the papers appear in appendices at the end of the document, after Chapter 5.

1.2. Context & Key Concepts

1.2.1. Diarrhea

Diarrhea is a leading cause of childhood morbidity and mortality (Liu *et al.*, 2015). It accounts for approximately 9% of all childhood deaths, making it the second leading infectious cause of death in children under 5 (Figure 1.2). This means that of the estimated 5.9M child deaths in 2015 (You D *et al.*, 2015), 531,000 of them were due to diarrhea.

Estimates show that 2% of diarrhea episodes progress to severe cases, with approximately 72% of deaths in children under-5 taking place in the first 2 years of life (Fischer-Walker *et al*., 2013). While the incidence of diarrhea peaks between 6 and 11 months, decreasing thereafter (Fischer-Walker *et al.,* 2012), the proportion of deaths are greatest between 0 and 11 months, when the risk of disease and severity are at their peak (Fischer-Walker *et al*., 2013).

Diarrhea is among the most common reasons for hospital admission in children in low- and middle-income countries (LMICs). It accounts for a large proportion of case visits seen at rural health centers. The greatest proportions of severe episodes of diarrhea occur in the South East Asian (26%) and African (26%) regions (Fischer-Walker *et al*., 2013). The highest numbers of deaths from diarrhea (about 50% of diarrheal deaths in 2011) occur in sub-Saharan Africa (Fischer-Walker *et al*., 2013). In Zambia, where childhood mortality rates are among the highest in the world (World Bank, 2014), diarrhea is the third leading cause of

childhood mortality, after pneumonia and malaria, with malnutrition and HIV/AIDS serving as important contributors (WHO, 2014; Thea, 1993; Baqui, 1993; Zacharof, 2001; Macwan'gi, 2008).

Although significant progress has been made in reducing diarrhea-related mortality, it remains a major cause of avoidable death. More than a decade has passed since the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) released a joint statement recommending low-osmolarity oral-rehydration salts (ORS) and zinc supplementation for diarrhea treatment in 2004, yet even today, many children in the developing world are not receiving these life-saving interventions. Oral Rehydration Salts (ORS) after each loose stool, until the diarrhea stops, and zinc supplementation for 10-14 days, are safe and effective in both home and facility settings when properly prepared and administered. Yet, of those children with acute diarrhea, less than 1% receives zinc and only a third receives ORS globally (Gill *et al.,* 2013). In Zambia, coverage estimates for zinc are in line with global figures at less than 1%, while ORS coverage has reached 62% (DHS, 2014).

Munos and colleagues assessed 205 developing country studies to review the efficacy and effectiveness of ORS and found that it reduced diarrhea specific mortality by 69% and rates of treatment failure by 0.2% (Munos *et al.*, 2010). Fischer-Walker and colleagues reviewed 13 zinc supplementation studies from developing countries and concluded that zinc supplementation for diarrhea management was associated with a significant reduction of 46% in all-cause mortality and of 23% in diarrhea-related hospital admissions. Zinc treatment

resulted in non-significant reductions in diarrhea specific mortality of 66% and diarrhea prevalence by 19% (Fischer-Walker *et al*., 2010).

Bhutta *et al.* modeled the benefits associated with three strategies (including the scale up of interventions for zinc and ORS, breastfeeding promotion, and case management of pneumonia) on the poorest quintiles through community-based platforms and showed that if 90% coverage were achieved for these three interventions, 64% of diarrhea deaths could be averted in the poorest quintiles in the three countries assessed (Bhutta *et al.,* 2013). This is in line with previous estimates which have demonstrated that more than three quarters of diarrhea deaths can be prevented with full coverage and utilization of ORS and zinc (Jones *et al.*, 2000).

Oral rehydration replaces lost fluids and essential salts thereby preventing or treating dehydration and the risk of death. Glucose contained in ORS enables the intestine to more effectively absorb the fluids and salts. Low-osmolarity ORS reduces the need for intravenous fluids (required in the most severe cases) and shortens the duration of diarrheal episodes (WHO, 2001). Zinc supplementation is added to ORS as an adjunct therapy and has been proven to decrease the duration and severity of diarrheal episodes, as well as the risk of subsequent infections in the 2-3 months following treatment (ZICG, 2000).

According to Fischer-Walker *et al.* (2009) many countries have been "stalled in the technicalities of adapting national policy for low-osmolarity ORS and zinc (ORS/zinc), while others struggle to find the funds for start-up activities". The problem is even worse in rural parts of the developing world, where for millions of people, ORS/zinc are often not available locally and are hard to come by, either

because of distance, cost, or because the supply has run out (Gill *et al.,* 2013; Werner & Sanders, 1997). In addition, there was a period where a movement towards integrated management of childhood illnesses moved the treatment of diarrhea away from the community and household level to facility-based care and often-incorrect case management (Bryce *et al.,* 2008). With a recent increased emphasis on integrated community case management (iCCM)[i] there may be a trend towards greater balance.

It has also been noted that providing ORSZ solely through public sector clinics has not been effective, comprehensive or sustainable in any country (Fischer-Walker *et al.*, 2009). Mothers and caregivers of children under 5 often face numerous opportunity costs associated with traveling to distant clinics, including taking time off work, paying for transportation, risks associated with treatment delay, etc. Thus, what may be needed to improve ORSZ usage in rural Zambia, and many other LMICs, is to make it available through the private sector at low cost. This could involve making the items available in local shops at the community level, or for distribution at the household level by community health workers. But it is important to keep in mind that need does not equate to demand. There are challenges associated with access, willingness to pay and utilization. Awareness is also generally an issue, particularly with regard to zinc. Mothers need to see the value and benefits of giving ORSZ to their children. They need to know when and how to use them, and where to get them. It has been suggested in recent calls for

[i] Integrated Community Case Management (iCCM) is a strategy to extend case management of childhood illness beyond health facilities giving more children access to lifesaving treatments. The iCCM package can differ by context, but typically focuses on diarrhea, pneumonia and malaria.

renewed action on ORSZ that the combined promotion of these two commodities is critical and may benefit from expansion to private sector markets, social marketing, and targeted behavioral change campaigns (Fischer-Walker *et al.,* 2009; Bhutta *et al.*, 2013). Even though there were successes in the promotion of ORS in the early and mid-1980s, strategies currently being used by countries, if at all, are in need of renewal. Combined packaging and promotion of ORS and zinc may help address some of these shortfalls.

1.2.2. Value Chains & Delivery

The application of business principles to global health is an evolving science. With increasing skepticism around conventional supply-chain systems used to deliver medicines in developing countries, there has been increasing pressure to learn from the commercial private sector (Ballou-Ares, 2008; Yadav, 2010). One promising approach to improving access and delivery of ORS and zinc involves blending concepts from health systems thinking and value-chain theory. Both emphasize a holistic way of viewing product/service delivery, and can help when attempting to analyze and address bottlenecks from both a supply and demand-side perspective. While value-chain thinking is commonly applied to FMCGs, it has not commonly been applied with regard to access to medicines, or to public health more generally.

A value-chain refers to the entire production chain from the input of raw materials to the output of final product consumed by the end user, with each link adding value to the original inputs (Dyer, 2000; Porter & Teisberg, 2006; Burns, 2002). In a value-chain, value flows back from the end-user as product is 'pulled' to

them. This is as opposed to traditional supply-chain systems, which tend to 'push' product out from the manufacturer toward the end-user. This is a key difference between value-chains and supply-chains – they flow in opposite directions (Feller *et al.,* 2006).

The primary focus of value-chains is on the benefits that accrue to end users, the interdependent processes that generate value, and the resulting demand and flow of funds created (Feller *et al*., 2006). In this way, value-chains can be thought of as an ecosystem of players, processes, information and resources required to effectively deliver a product/service from its conception to the end user. These "end-markets" determine the characteristics of the final product/service, with their demands and specifications driving quality and standards (Lusby & Panlibuton, 2006). Thus, understanding the demands and trends of the end market is central to the value-chain.

Kim, Farmer and Porter (2013) note that the biggest obstacle facing global health is a failure of delivery. They note that:

> *The gritty business of actually delivering health care in developing countries has not attracted much academic interest, even though improving capacity to deliver care in these settings will save lives, leverage substantial and growing philanthropic support of global health, and increase returns on existing and new investments in both discovery and development of new resources.*

They emphasize care delivery value-chains as a corner stone of their strategic framework for global health delivery, which defines core principles that underpin a high-value delivery system and its component parts. These include: 1) use of care delivery value-chains (CDVC), 2) shared delivery infrastructure, 3) aligning delivery with external context, and 4) leveraging the health-care delivery system for economic and social development (Kim *et al*, 2013). The ColaLife

approach considered all of these principles in different ways. Appendix 1 summarizes the various ways in which the four components of the framework were addressed. Kim *et al.* note that by focusing on the design and operation of delivery systems, greater attention is paid to developing systems that may be brought to scale.

1.2.3. Integrated Innovation & Health Markets

The relatively new concept of "integrated innovation" focuses on "the coordinated application of scientific/technological, social and business innovation to develop solutions to complex challenges (Singer *et al.,* 2010)." This approach emphasizes the synergies that can be achieved by harnessing all three types of innovation, rather than focusing on the individual benefits of each alone. It recognizes that public health innovations have a greater chance of achieving sustainability, global impact and scale, if from the outset, they are developed with the appropriate social and business considerations (Singer *et al.,* 2010).

Similarly, in their discussion of the growing interest in social entrepreneurship in health-markets, Bloom *et al.* note that the term social entrepreneurship refers to "organizations that borrow a mix of business, charity and social movement models to reconfigure solutions to community problems and deliver sustainable new social value (Nicholls, 2006)." Both Austin *et al.* (2006) and Nicholls[2] note that social entrepreneurs often work across the public, private and social sectors, which Bloom *et al.* note makes them particularly interesting in the context of marketized health systems (Bloom *et al.*, 2009).

From a global health policy perspective, interventions that harness these

sister concepts, while applying a health market lens are currently of particular interest and promise. A recent report from the Center for Health Market Innovations (CHMI) noted that, "When well-monitored and regulated, health markets can be a source of creative new approaches with the potential to achieve greater efficiencies, improved quality, and increased access to care for underserved populations (2011)." However, the report notes that few innovative programs are ever evaluated to academic standards and the evidence base for such programs is still lacking (CHMI, 2011). In sharing key expert recommendations from a recent Health Market Symposium held in Bellagio, Peters and Bloom reiterate the need for a "major effort by all market players to test innovative business models to improve access to safe and effective health services in the developing world (Peters & Bloom, 2013)."

Bloom and colleagues' description of health markets (2009) centers around the supply (by providers) and demand (by consumers) of health goods and services as the basis of a market system. Building on Elliot's model (2008), they highlight the many stakeholders and roles involved in the health market system including: informal networks, the private sector, NGOs, and Government; various support functions (i.e. management of various inputs like drugs); as well as the rules (both formal and informal) that influence the system and individual behaviors.

Peters, Paina and Bennett (2012) observe that due to discrepancies between health needs and demands, the information asymmetry pervasive in the health sector, and the challenge for institutions to maintain/apply rules, health market systems require intervention to minimize/mitigate the effects of market failure (Arrow, 1963; Bloom *et al.*, 2011). Given the complexity and variability related to organization of a health market, the design of a health market intervention often

relies on the characteristics of the health commodity (Bloom *et al.,* 2009 or Peters & Bloom, 2013). Some are only affiliated with minimal information asymmetry, facilitating consumer use with little expertise and posing low risk. One of the differences between these and more complex health goods relates to knowledge, trust in the provider, effort, and the users' ability to pay. For example, a relatively easily treatable disease like diarrhea simply involves access to a combination of good quality drugs (ORS and Zinc) and information, some of which is already well known, at least with regard to ORS (DHS, 2014). Bloom *et al.* suggest that these situations may be best left to competitive markets, and confirm that, "the main challenges are to develop a well-defined good and/or service, establish a distribution system, and inform potential users of its value. One example is the development and widespread use of oral rehydration solution for diarrhea" (2009). They add that a program focused on strengthening health market systems for the poor needs to identify and disseminate innovations by the poor. These innovations are also more likely to develop closer to where the poor live. Co-production with provider organizations and other agencies is essential in this task (Bloom *et al.,* 2009).

1.2.4. Zambia

Research was carried out across 4 rural districts of Southern and Eastern Province, Zambia (Figure 1.3). Zambia is a landlocked nation in sub-Saharan Africa bordered by Mozambique, Zimbabwe, Botswana and Namibia to the South, Angola to the West, Democratic Republic of Congo and Tanzania to the North, and Malawi to the East. With a gross national income (GNI) per capita of approximately $3860 (PPP,

International dollars) in 2014 (World Bank, 2014) Zambia has seen steady growth over the past decade, but has seen a weakening of the economy and a drop in the value of the Kwacha in 2015. Regardless, the gains experienced over the past decade have failed to translate into reductions in poverty. With 42% of the population living in extreme poverty, the absolute number of poor increased from 6M in 1991 to 7.9M in 2010, mainly due to population growth (World Bank, 2015). Providing basic health services and essential medicines to most of the population, particularly the rural poor, remains a challenge.

Limited data exist with reference to private sector health providers in Zambia, let alone the rural retail sector. This is partially due to the fact that there is limited private sector health provision in the country overall. The same applies to the provision of Public Health Products (PHPs) like ORS and zinc. PHPs are defined as products used for promoting health or for the prevention, management or treatment of diseases of public health significance. These can typically be provided at the general retail level without the delivery of an associated service (Conteh & Hanson, 2003). Additional examples of PHPs and their characteristics are provided in Tables 1.1 and 1.2.

In rural areas, the vast majority of access to health products and services tends to be limited to public sector facilities. With few exceptions, PHPs such as ORS and zinc can only be obtained from rural health centers or posts. Of the 1,956 health facilities in the country as of 2012, the government runs 81% (1590), the private sector runs 13% (250), and 6% (116) are faith-based facilities (Ministry of Health, 2013). These facilities include 307 (16%) rural health posts, 1,131(58%) rural health centers, 409 (21%) urban health centers, 84 (4%) district level hospitals, 19 (1%) provincial or general hospitals, and 6 (0.03%) large, tertiary care hospitals.

The Government of the Republic of Zambia's (GRZ) access policy states that there should be a health facility within 5km of every household. While this is indeed the case for 99% of urban households, it is only the case for 50% of rural households (Chankova and Sulzbach, 2006). While the GRZ's strategic plan was to increase access to 70% of the population by 2015, the target was not achieved. There are a number of difficulties to accessing healthcare in rural areas. Key barriers to physical accessibility were cited as: "insufficient infrastructure; inaccessibility due to geographic factors; sparsely distributed population in rural areas; inadequate resources for outreach (fuel, vehicle, bicycle, motor-bikes, boats); and poor scheduling of services leading to missed opportunities" (Ministry of Health, 2011). Access of the health supply chain tends to be limited beyond the rail line and there is poor availability to service delivery points (Ballou-Ares *et al.,* 2008). One rural Zambian study found that distance was a significant predictor of attendance for diarrhea treatment specifically (Chatt and Robert, 2010).

In addition to geographic access barriers, public sector facilities face regular stock outs of essential medicines like ORS and zinc. Thus, despite basic medicines being made available at no cost to patients as of 2006 (Masiye *et al.,* 2010), essential and life-saving drugs were still widely unavailable in health facilities according to a nationally representative Public Expenditure Tracking Survey (Picazo and Zhao, 2008). Analysis of recent Health Metrics and Evaluation (IHME) data (IHME, 2015) from Zambia found that 23% of rural health centers surveyed (n=363) reported having stock-outs of ORS within the previous year, while 30% reported having zinc stock outs. Nationally, 11% of rural health centers surveyed were stocked out of ORS on the day of visit, while 54%

were out of zinc. Even when zinc is available at health centers, utilization rates of less than 1% across the country would indicate healthcare workers rarely prescribe it.

The supply chain for medicines to Zambian health facilities is largely dependent on a three-tier public sector distribution system. Products are procured by the Central Medical Store (CMS) and channeled down to service delivery points on a monthly basis. Virtually all of the public sector supply, and much of the faith-based facility supply, comes from international suppliers and procurement agents, and is then pushed through the system (Dalberg, 2008). Primary distribution of drugs and other commodities from Lusaka to about 120 district medical stores (DMS) and hospitals is managed by a parastatal called Medical Stores Limited (MSL). The secondary distribution of commodities from district stores to health facilities then falls under the purview of District Health Management Teams (DHMTs) who report to the MOH (Vledder *et al*., 2015). While MSL's trucks do a good job of getting products to the district level, multiple field studies conducted between 2006 and 2008 (Beers, 2007; Dalberg, 2008; Picazo and Zhao, 2008, Yadav, 2007) identified the key reasons for stock-outs as lying beyond the district level. These included secondary distribution not being carried out in a uniform way across the country, with many health facilities having to travel to their district headquarters to pick up stock themselves (Yadav, 2015). In addition, transportation is a significant challenge within the secondary distribution system with insufficient vehicles, regular breakdowns due to poor roads and high usage, and poor accessibility due to seasonal weather conditions. Other challenges identified included difficult communication between the District Central Store and health centers who typically rely on radio systems and personal cell phones, as well as a lack of demand data resulting in supply decisions not being based on actual consumption patterns.

Private sector supply chain channels have yet to play a significant role in the country's health sector, and less is known about their structure and operations when compared to the public sector supply chain (Palafox *et al.,* 2012). That said, the MOH is supportive of private sector initiatives and in 2009, launched phase two of the Private Sector Development Reform Program. This program aims to expand and accelerate private health sector growth (Kwesiga *et al*., 2010).

As in many developing countries, access to medicines in the private sector is currently largely confined to urban settings and is very limited in rural areas (Goodman, 2004; McCabe *et al*., 2011; Yadav *et al*, 2012; Cohen *et al*., 2010; Wafula *et al*., 2012). Much of the private sector access that does take place is through pharmacies and drug shops. The fact that there are less than 100 pharmacists (i.e. Bachelor of Pharmacy) in Zambia and only 59 pharmacies (40 of which are in Lusaka) contributes to this confinement. Similarly, the lack of pharmacy technicians (i.e. diploma in pharmacy) in the country keeps the number of drug shops low as well (Dalberg, 2008). All private pharmaceutical importers, wholesalers, and retail pharmacies in the country are required to employ a pharmacist registered with the Medical Council of Zambia (Palafox *et al.,* 2012). Pharmacy technicians too should be registered with the Medical Council of Zambia. Licenses for the manufacturing, importation, wholesale and pharmacy retail of medicines are issued by the Zambian Medicines Regulatory Authority (ZAMRA, previously the Pharmaceutical Regulatory Authority or PRA). The functions of the Authority as stipulated by the Medicines and Allied substances Act of 2013 includes the regulation and control of the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances. It covers the registration of products,

pharmacies, health shops and agro-veterinary shops. It is also responsible for post-marketing surveillance.

Drug shops, registered with local governments rather than licensed by ZAMRA, are not required to employ a pharmacist. While they are only supposed to dispense over-the-counter medicines, in practice, they also dispense prescription only medicines. These retail outlets are mostly limited to urban centers. Medicine prices and mark-ups within these private sector outlets are not regulated and are established by the market.

General stores that focus mainly on the sale of FMCGs are another source of a limited number of over-the-counter medicines. Very little is known about these outlet types, and the literature on their characteristics and behaviors in Zambia is extremely limited. After manufacturers, importers, distributors and wholesalers, these retailers, and the consumers that buy from them, constitute the end of the value-chain for a number of FMCGs *(*Paper 3; Patouillard *et al.,* 2010; Palafox *et al*., 2014). In contrast to the shelves at many clinics, the shelves of these entrepreneurs, that live and work at the community-level, always seem to be full of products. It has been suggested, that expanding access to treatment for diarrhea could benefit from private sector, market-based approaches (Fischer-Walker *et al*., 2009; Gill *et al*., 2013). The World Health Organization (WHO) and UNICEF advocate strategies to improve home-based management of diarrhea (UNICEF/WHO, 2009), with retailer interventions seen as one possible facilitator. ORS and zinc can be taken without much guidance or with simple instructions; there is minimal risk associated with their use (e.g. no threat of resistance); and they are recommended regardless of the causal agent. Timely and appropriate treatment of children under-5 years of age is particularly important in preventing dehydration and

curtailing morbidity and mortality. Providing care through such retailers, closer to the household level, may be one way of addressing this.

1.3. Aims & Objectives

1.3.1. Project Objectives

The primary objective of the ColaLife trial was to increase effective use of ORSZ for home treatment of acute diarrhea in children under the age of 5 in rural Zambia, ultimately helping to reduce diarrhea-related child mortality. The logic model developed for the evaluation of the project (Appendix 2) helps describes the theory of change, including an overview of the activities, outputs, immediate and intermediate outcomes, as well as the primary objective and expected ultimate impact.

The model is divided into three key streams of work, namely: [A)] the supply chain stream; [B)] the knowledge, attitudes and practice stream; and [C)] the knowledge translation stream. All three streams were to work in unison to lead to the final impact of contributing towards MDG 4/SDG 3.2 – a reduction in child mortality. In addition, the program exemplifies a key tenet of SDG 17 – strengthening the means of implementation and revitalizing global partnerships for achieving the goals and sustainable development more generally, especially with regard to providing access to affordable, essential medicines in developing countries (SDG 3.b). Given the required timelines and resources associated with effective measurement of mortality impact, analysis at this level was deemed to be out of scope for the

evaluation, and measurement therefore ended at the intermediate outcome level of *utilization*.

Key inputs for the trial included funding [e.g. Department for International Development (DFID) UK, Grand Challenges Canada, Johnson & Johnson Corporate Citizenship Trust], program policies being established, planning conducted during the design phase, commodities (e.g. packaging, ORS, zinc, soap, pamphlet, etc.), relevant country policies (e.g. over the counter zinc status), coordination processes during the project, as well as the relevant human resources and expertise required to make the program successful.

Key activities/processes for streams A and B included development of the Kit Yamoyo, including procurement of the contents, pricing, testing, and detailed co-design with end-users. In addition, it involved operationalizing the value-chain developed with the relevant program partners. Closely related to this activity were the awareness raising, recruitment and training of retailers and wholesalers that made up key components of the value-chain. A final key activity was the social marketing campaign associated with the Kits, including the design, testing and delivery of information, education, and communication (IEC) materials. This took place at the level of the product itself (i.e. instructional pamphlet/branding) and at the community level (e.g. within local shops, collaboration with health centers, over radio, via posters, and through workshops and community drama events run by trained promoters). Because measurement and development of a strong evidence base is essential for any potential future scale-up and knowledge generation, key activities within stream C included implementation of the monitoring and evaluation (M&E) plan, execution of an open innovation process (e.g. leveraging of

Social Media tools) as well as the development of a sustainability strategy (e.g. gradual transition to private sector partner – Pharmanova).

These activities were expected to lead to important outputs in each stream. Stream A outputs, which fall within the scope of this dissertation, included Kits meeting the needs at all levels of the value chain (i.e. mothers/caregivers, children, health centers, distributors, retailers); effective operation, flow and quantities within the supply chain to rural communities; as well as retailers and health centers being effectively trained in the benefits and methods associated with the Kits. For the retailers, this included tracking of stocks and sales, how to redeem vouchers, and para-skilling/training with regard to diarrhea treatment guidance. The central stream B output was that the social marketing campaign, as well as the IEC materials, were effectively developed and implemented. The effective implementation of a well-designed M&E plan was the key output for stream C.

All communities targeted were located in underserved/rural areas. In terms of immediate outcomes, stream A was to result in improved *availability* of the contents of Kits in underserved communities. Stream B was to result in increased awareness of Kits and the health benefits of the contents among target audiences. For stream C, the immediate outcomes were to determine a sustainability strategy, as well as the collection and analysis of relevant data. Both streams A and B were expected to help lead to the intermediate outcome of improved *access* to the combination therapy of ORSZ, and then to the purpose (i.e. final outcome) of caregivers of children under 5 increasing *use* of ORSZ for household treatment of diarrhea.

Stream C's intermediate outcome is that important lessons learned are disseminated, the sustainability strategy implemented, and an official multi-sectoral partnership established for last-mile delivery and scale-up if warranted.

1.3.2. Research Questions

The current dissertation research was derived from the above framework of the overall project. While there are many interesting research questions to be explored relating to the value-chain approach undertaken, the research questions that form the basis for this dissertation address some of the most important questions from a public health perspective. The specific research questions that will be explored as part of this research proposal include:

Question #1: Does emulating the commercial, private-sector value-chains of fast moving consumer goods (FMCGs), such as Coca-Cola, and applying lessons to the introduction of an innovative diarrhea treatment kit, have an effect on coverage of ORS and zinc at the community-level?

Question #2: To what extent can consideration of human-centered design – through a focus on product-oriented, demand-related dimensions of access (e.g. acceptability) - lead to improved product innovation, appropriate utilization (i.e. rational use) and perceived efficacy of public health commodities such as Oral Rehydration Salts (ORS)?

Question #3: What are the characteristics and operations of rural, commercial, community-level, general retail shops that commonly specialize in the sale of fast-moving consumer goods (FMCGs)? What insights can be drawn that may inform

their use as informal private 'providers' of public health products (PHPs)?

1.4. Conceptual Frameworks

The ColaLife distribution system (Figure 1.4) started with Pharmanova, a Zambian pharmaceutical company and the key private sector partner based in Lusaka. They were responsible for manufacturing (e.g. ORS) and procuring (e.g. zinc, soap, container) Kit Yamoyo components (as of 2015, they also started manufacturing the zinc), assembling and storing the Kits, and then delivering the Kits to Medical Stores Limited (MSL), a government parastatal responsible for delivery of drugs in the public sector. MSL was then responsible for storage and delivery of the Kits to the intervention districts (Kalomo and Katete) on a monthly basis. Rather than MSL delivering the Kits to a district medical storage facility (as with the public sector), they delivered the Kits to the Coca-Cola wholesaler located in the district towns.

These independent wholesalers typically sell numerous other FMCG's, along with being the exclusive district-level distributors of Coca-Cola. Once the Kits were available from the wholesaler, they were free to be purchased by registered Kit Yamoyo retailers. This restriction was only in place for purposes of the trial's operational research and has since opened up to all retailers interested in carrying the product. Retailers then purchased the kits from wholesalers, and took the Kits back to the community level for sale in their shops, thereby opening up new points of treatment access for caregivers in rural Zambia. These private sector access points were closer to homes and provided the necessary tools for effective treatment of diarrhea.

Bigdeli *et al.* (2012) highlight the fact that most health systems strengthening interventions ignore interconnections between different system components. Consequently, they note that access to medicines at the population level are addressed mainly through fragmented often vertical approaches that focus on supply alone, and not wider issues of access to health services and interventions.

Traditional access to medicines frameworks have attempted to break down the various dimensions and determinants relating to supply and demand of medicines (Table 3.1). Through their 'access to medicines from a health systems perspective' framework, Bigdeli *et al.* build on these dimensions and determinants by proposing a more holistic view of both supply and demand-side factors, as well as consideration of several dynamic relationships between medicines and other health system resources. If one were to generalize Figure 1.4 (ColaLife Distribution Structure) and consolidate it with the elements of Table 3.1 (Access Frameworks), exploring the ColaLife model from a health systems perspective, the resulting conceptual framework would be Figure 1.5 (Access to Medicines from a Health Systems Perspective). While the project has been working at multiple levels within this framework, the key intersections relevant to this dissertation have been highlighted in relation to the previously identified research questions which operate at the key intersections of:

- Service delivery, and individuals, households and communities – Question #3;
- Market forces, innovation, and resources (particularly with a focus on the attributes of acceptability of medicines) – Question #2; as well as
- The overall value-chain approach, which attacked the problem of diarrhea by acting at all key junctures thereby addressing multiple challenges and

bottlenecks within the system, but measuring the key outcome of coverage – Question #1.

Complementing the access to medicines frameworks and dimensions is the Innovation, Adoption, Diffusion Model by Rogers and Shoemaker (1971). Their classic model identified five key categories of characteristics for consideration with regard to the rate of innovation diffusion. These included: 1) perceived attributes of the innovation (relative advantage, compatibility, trialability, observability, and complexity), 2) communication channels (e.g. mass media, interpersonal, etc.), 3) nature of the social system (e.g. norms, degree of network interconnectedness, etc.), 4) extent of change agents' promotion efforts, and the type of innovation-decision being made (e.g. optional, collective, authority). These factors were also considered during implementation and were active elements of the overall intervention evaluated in Paper #1.

Paper #2 focuses on the human-centered design of the product innovation at the heart of the overall intervention. Moultrie and colleagues (Moultrie *et al,* 2006) identify several "good design" features that influence product desirability. These features draw many parallels with the perceived attributes of an innovation from the Rogers and Shoemaker framework, and include: usability, core benefits, aesthetics and sensory appeal, symbolic value, and product novelty/differentiation. Figure 1.6 draws on these attributes as well as those from the acceptability dimension from various access to medicines frameworks (Frost & Reich, 2010; Center for Pharmaceutical Management, 2003; WHO, 2004), to establish the

conceptual framework for Paper #2 with the key outcome variables being appropriate use of ORS and its perceived efficacy.

Variables of interest for Paper #3 were mainly identified based on market research frameworks and factors explored in other retailer-focused studies, both within healthcare and general retail sectors (Kumar, 2013; Cheungsuvadee, 2006; Carpenter & Moore, 2006, McCabe, 2011, Wafula *et al.*, 2012). Key variables of interest explored included: demographic information related to shop owners and proprietors, physical aspects of the shop, sales and stocking patterns, procurement practices including wholesaler preferences (i.e. source of goods), product choices (including medicines), pricing and profits, and information relating to the customer base. Based on a review of the literature, understanding these elements of rural, commercial general retailers was considered to be a sound way of exploring their potential as informal private providers of PHPs from a descriptive perspective.

1.5. Study Design & Data Sources

The overall evaluation of the ColaLife trial used a quasi-experimental pretest-posttest design with matched comparators. The data for the specific studies which make up this dissertation were derived from different components of the overall design. The main data sources include cross-sectional, rural household surveys conducted in 2012 (baseline) and 2013 (endline), as well as retailer surveys conducted in 2012 (midline) and 2013 (endline). Household Questionnaires were administered to 2458 and 2477 caregivers of children under 5, across 4 rural districts of Zambia, at baseline and endline, respectively. Retailer surveys were administered to 180 retailers across the four districts during each data collection

period. Two districts (Kalomo and Katete) served as intervention districts, while the other two (Monze and Petauke) served as matched comparators.

Paper #1 uses logistic regression analysis to calculate the adjusted relative risk of combination therapy use in intervention districts vs. comparator districts at endline. Secondary analysis used difference-in-differences estimation to compare ORS use (with or without zinc) in the intervention and comparison districts, before and after market-shaping activities. Because zinc use was close to nil at baseline, a difference-in-differences analysis to test the change in combination therapy was deemed inappropriate.

Paper #2 compared correct preparation of ORS for children under 5 with diarrhea, who either used Kit Yamoyo or standard one-liter sachets of ORS from rural health centers. Data drawn from the endline survey were analyzed using logistic regression and calculated the odds of correct preparation of ORS (i.e. concentration) in Kit users vs. non-users. Secondary analysis examined to what extent preparation of ORS in the correct concentration was associated with a change in the odds of perceiving ORS as effective.

Paper #3 is predominantly descriptive in nature. It uses retailer survey data from 180 interviews of general, community-level retailers who commonly sell FMCGs, to explore the potential of using them as outlets for provision of basic public health products like ORS and zinc. Findings were grouped under key themes including: infrastructure, staffing, ownership and operations, purchasing patterns, product preferences, and level of engagement with an intervention to expand coverage of a newly introduced diarrhea treatment kit. Additional details relating to the methods of for each paper have been integrated into the specific chapters.

Figures for Chapter 1

FIGURE 1:1: ORIGINAL KIT YAMOYO (AIDPOD)

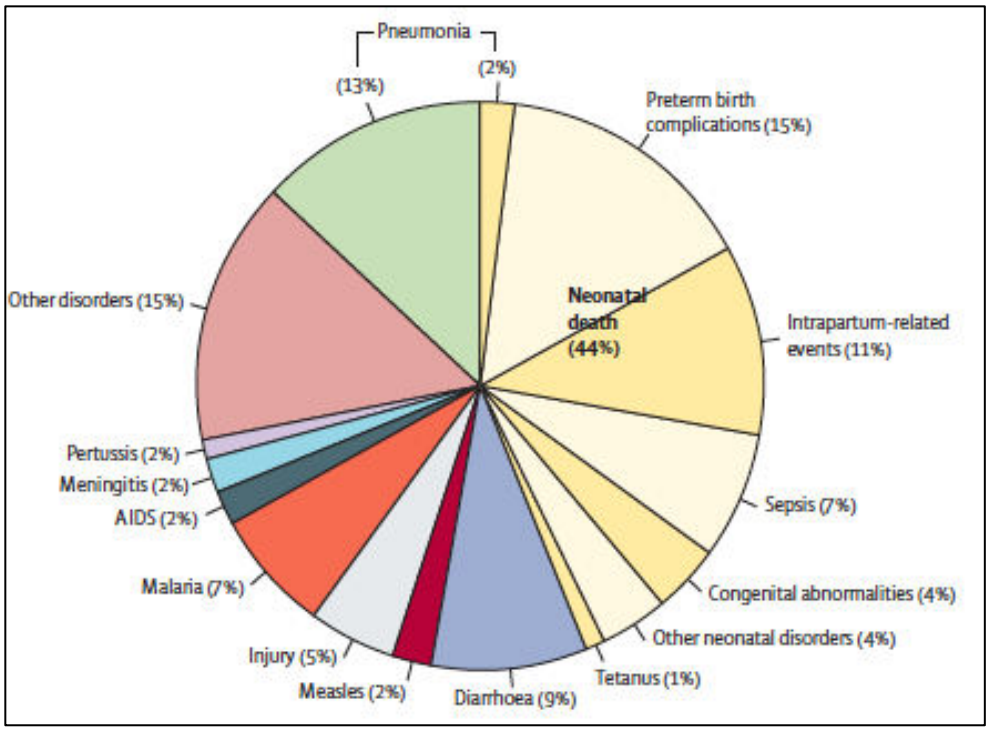

FIGURE 1:2: GLOBAL CAUSES OF CHILDHOOD DEATHS IN 2013 (LIU *ET AL.*, 2015)

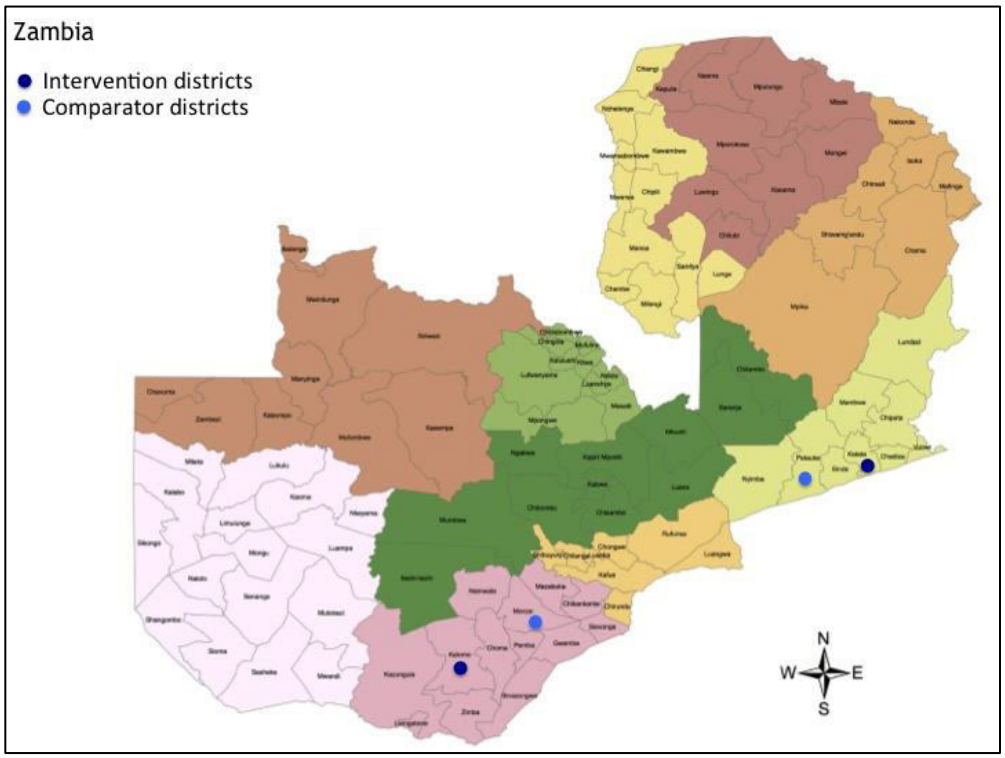

FIGURE 1:3: ZAMBIA PROJECT DISTRICTS

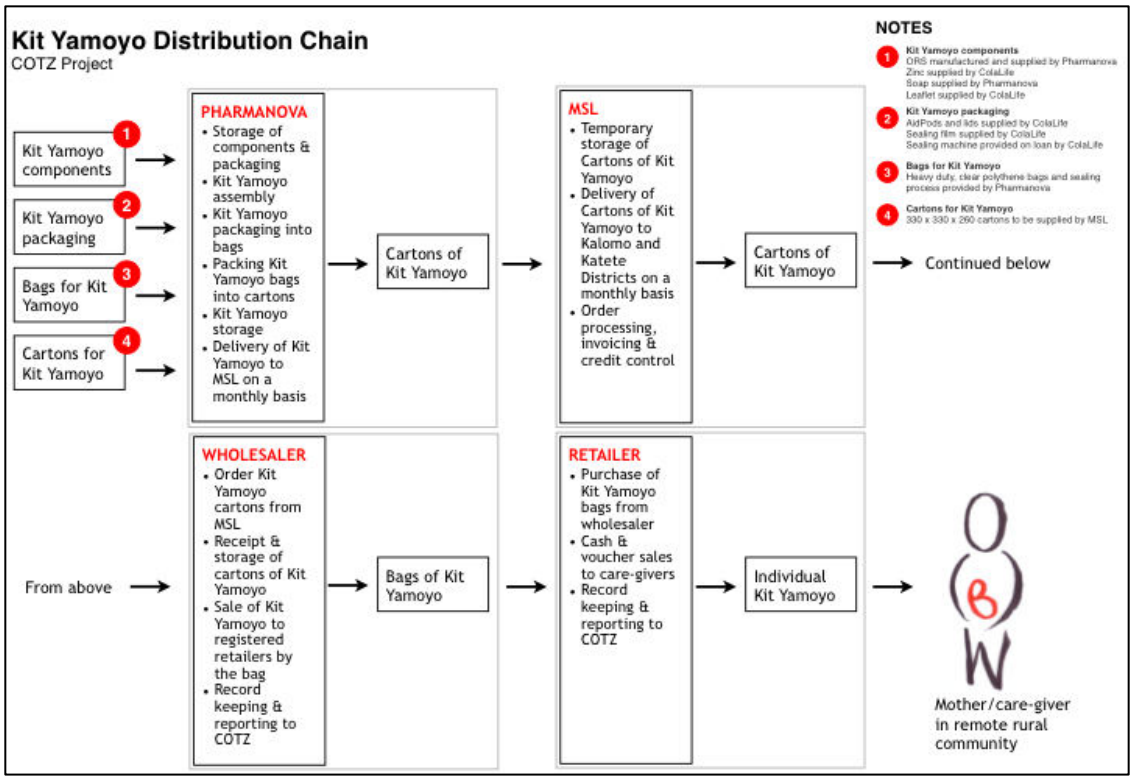

FIGURE 1:4: COLALIFE DISTRIBUTION STRUCTURE (SOURCE: COLALIFE)

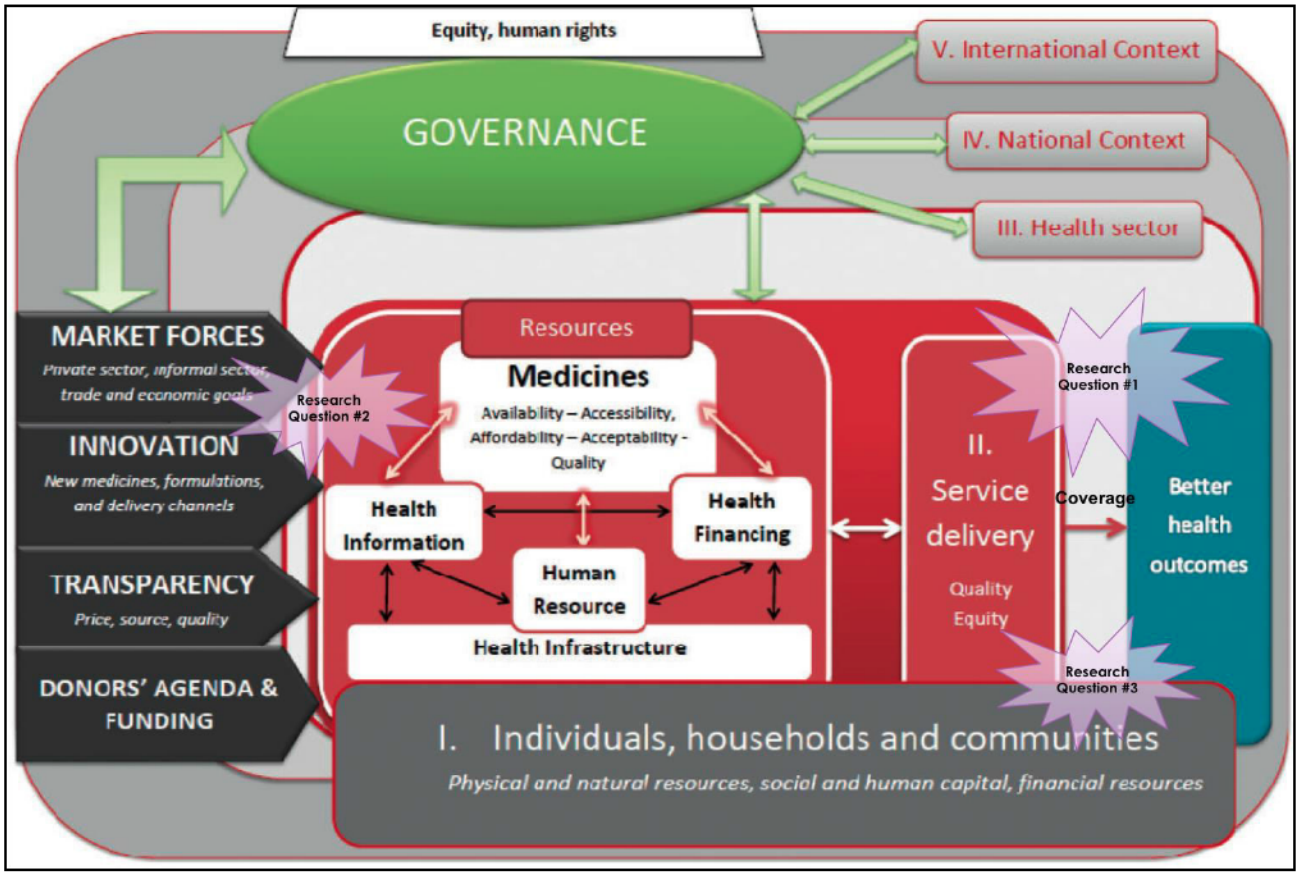

FIGURE 1:5: ACCESS TO MEDICINES FROM A HEALTH SYSTEMS PERSPECTIVE (SOURCE: ADAPTED FROM BIGDELI *ET AL.*, 2013)

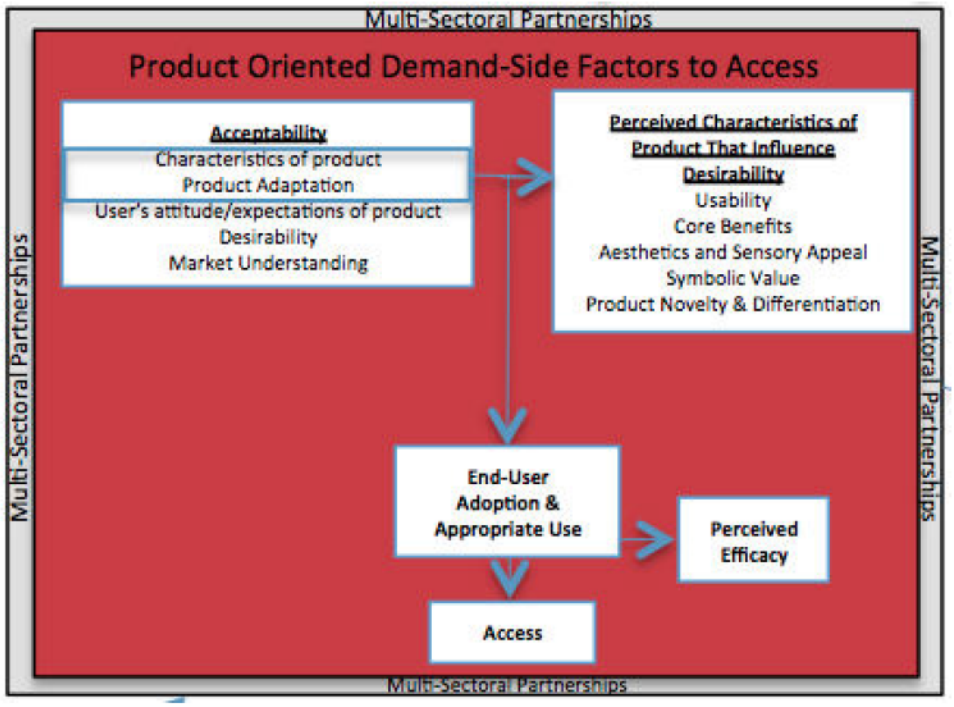

FIGURE 1:6: PRODUCT ORIENTED DEMAND-SIDE FACTORS TO ACCESS FRAMEWORK

Tables for Chapter 1

TABLE 1.1: EXAMPLES OF PUBLIC HEALTH PRODUCTS (PHP)

Global Health Focus	**PHP***
STIs	Condoms
Malaria	Antimalarial drugs * rapid diagnostic tests (RDTs)
Malaria	Mosquito nets and insecticide for re-treatment
Family Planning	Various contraceptives
Variable	Some antibiotics (e.g. Amoxicillin for Pneumonia)
Diarrhea	ORS
Diarrhea/Pneumonia	Zinc
Helminth Infection	De-worming tablets (e.g. albendazole)
Hygiene & Sanitation	Water purification devices
	Sanitary pads
	Clean birthing kit
	Soap
Healthy Growth, Development, & Prevention of Deficiencies	**Micronutrients**
	Iodized salt
	Vitamin A
	Iron folate
	Prenatal Vitamins

*'Positive perspective' would suggest that any *products that are in practice sold as commodities, whether legally or not, should be considered to be PHPs (antimalarials, antibiotics, and oral contraceptives)*

TABLE 1.2: CHARACTERISTICS OF PUBLIC HEALTH PRODUCTS

Characteristic
Can be distributed through the private retail sector as well as through the formal health system.
Have a significant 'private good' with significant share of benefit accruing to the end-user (excludable, rival and rejectable)
Supply of many PHPs faces relatively low barriers to entry and exit, so that markets are contestable (e.g. do not require very specific assets; few or no sunk costs; and no natural monopoly issues)
Most purchases of PHPs are discrete, time bound, and do not require an ongoing relationship with the retailer
PHPs have the characteristic of 'measurability' (i.e. easy to measure with precision and therefore compare across products and sellers to find best deal)
Problem of information (i.e. asymmetries between seller and consumer; level of knowledge of retailer, etc.)
Problem of controlling price and ensuring affordability and purchasing power

Based on reasons why competitive markets have tended to emerge (Berman, 2000; Preker & Harding, 2000; Conteh & Hanson, 2003).

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Chapter 2 - Impact of Emulating Commercial, Private-Sector Value-Chains on Uptake of ORS and Zinc for Childhood Diarrhea in Rural Zambia: Evaluation of the ColaLife Trial

Abstract

Globally, diarrhea remains a leading cause of avoidable morbidity and mortality in children under 5. The inability to effectively access the globally recommended treatment – ORS and zinc – has contributed to poor coverage levels in most of the developing world. Weak supply-chains and low-uptake have been identified as priority bottlenecks.

Market-based solutions that engage the private sector and simultaneously stimulate both supply and demand of these essential commodities have been recommended as a way of overcoming such barriers. We hypothesized that emulating the commercial, private-sector value chains of fast moving consumer goods (FMCGs), and applying lessons to the introduction of an innovative diarrhea treatment kit would increase coverage of ORS and zinc at the community-level. Through public-private partnerships between community-based retailers and community health workers/promoters at the micro-level, and between the Ministry of Health, a local pharmaceutical manufacturer (Pharmanova), SABMiller (The Coca-Cola Company's bottling partner in Zambia), pi Global (packaging design firm) and a range of other local and international stakeholders at a macro-level, we emulated value-chain principals used by Coca-Cola. This included tapping into the same distribution channels that make FMCGs available in rural communities in many low and middle-income countries.

We tested the impact of this approach on uptake of ORS and zinc in children under 5 suffering from diarrhea in rural Zambia. Using a quasi-experimental pretest-posttest design with matched comparators, we conducted household surveys of 2458 and 2477 caregivers of children under 5 at baseline and endline, respectively. Surveys were conducted across 2 intervention districts, each with a matched comparator district. Use of ORS and zinc combination therapy increased from less than 1% at baseline to 46.6% across the intervention districts, while no

change was seen in the comparator districts (Pooled Risk Ratio: 39.0; 95% CI: 13.2-115.2; p<0.001). Difference-in-differences analysis comparing ORS use (with or without zinc) in the intervention and comparison districts, before and after market-shaping activities, found that pooled ORS use increased significantly across intervention districts from 59.8% to 76.4% (OR: 2.17; 95% CI: 1.47-3.24; p<0.001), while usage across comparators decreased non-significantly from 66.4% to 58.2% (OR: 0.71; 95%CI: 0.48-1.04; 0.08).

Key Words: Value-Chain, Supply-Chain, Public-Private Partnership, Diarrhea, ORS, Zinc, Retailers, Coca-Cola, ColaLife

Introduction

Globally, diarrhea remains one of the leading causes of avoidable morbidity and mortality in children under 5 (Fischer-Walker *et al.*, 2013; Sabot *et al.*, 2012; UNICEF 2009;). It is the second leading infectious cause of childhood mortality, and accounts for approximately 9% of all under-5 deaths (Liu *et al.*, 2015; UNICEF 2012). In Zambia specifically, childhood mortality rates are among the highest in the world (World Bank, 2014), with diarrhea accounting for approximately 9% of deaths in children under-5 (WHO, 2015). This makes it the third leading cause of childhood mortality in the country, after pneumonia and malaria, with malnutrition and HIV/AIDS serving as important contributors (Thea *et al.*, 1993; Baqui *et al.*, 1993; Zacharof, 2001; Macwan'gi & Phiri, 2008).

These statistics exist within the context of national policy makers and the global health community knowing well what is required to reduce childhood deaths from diarrhea (Fischer-Walker *et al.*, 2009; Bhandari N *et al.*, 2008; Awasthi S *et al.*, 2006; Hamer D *et al.*, 1998). Oral Rehydration Salts (ORS) after each loose stool,

until the diarrhea stops, and zinc supplementation for 10-14 days, are safe and effective in both home and facility settings when properly prepared and administered. They are off-patent; can be manufactured cheaply; do not require cold chains; only need to be taken episodically and for relatively short durations; are extremely cost-effective; and with relatively low technology demands, can be manufactured locally provided principles of Good Manufacturing Practices are followed (Gill *et al.,* 2013; Baqui *et al.*, 2002; Yakoob *et al.*, 2011; Mazumder *et al.*, 2010; Munos *et al.*, 2010; Fischer-Walker & Black, 2010; Bhandari *et al.*, 2008; Bishai *et al.*, 2013; WHO, 2006; Fischer-Walker *et al.*, 2009). In Zambia, they also both have over-the-counter status. Nonetheless, despite efforts of international health agencies to promote home use of these treatments, they still remain underutilized. Of those children with acute diarrhea, less than 1% receives zinc and only a third receives ORS globally (Gill *et al.,* 2013). In Zambia, coverage estimates for zinc are in line with global figures at less than 1%, while ORS coverage has reached 62% (DHS, 2014).

Barriers to effective access for these commodities relate both to supply and demand. The most pressing challenges identified in the reduction of childhood deaths from diarrhea include insufficient access, production, distribution and promotion of key commodities like ORS and Zinc (Gill *et al.,* 2013). These challenges are consistent with those identified over the past decade (Bryce *et al.,* 2005; Bhutta *et al.,* 2010; Fischer-Walker *et al*., 2009). In Zambia, and many other developing nations, the problem is compounded in rural areas, where the burden of diarrhea is often greatest. Here, the public sector struggles with "last-mile" logistics for essential drugs. Delivery beyond district level warehouses to health facilities is

typically non-existent or unreliable (Yadav, 2015). Sparse populations, insufficient infrastructure, geographically disbursed health facilities, poor transportation infrastructure, inadequate resources for outreach (fuel, vehicles, etc.), and inaccessibility to certain areas during the rainy season are all contributing factors (Vledder M *et al.*, 2015; MOH, 2011). In addition, medicine supply-chains within the public sector are often weakened by uncertainties in financing, long resupply intervals, a lack of continuous stock-out and consumption information for planning, and lack of incentives for supply-chain staff (Yadav, 2015).

Similar challenges have been reflected as top research priorities for childhood diarrhea. The key research theme identified as part of the Global Action Plan for Childhood Diarrhea, for example, was the need to substantially increase the delivery and use of ORS and zinc, as well as to identify those factors that supported and interfered with their proper use (Zipursky *et al.,* 2013). Fischer-Walker and Black specify that knowledge is lacking with regard to the best delivery strategies and how to introduce zinc into health systems that already struggle with coverage of ORS (Fischer-Walker & Black, 2014).

In *rural* Zambia, availability of ORS and zinc is largely limited to a reliance on public supply-chains. With few exceptions, access in these areas remains limited to often-distant health facilities alone. The Government's access policy states that there should be a health facility within 5km of every household. While this is indeed the case for 99% of urban households, it is only the case for 50% of rural households (Chankova and Sulzbach, 2006). Stock-outs of both ORS, and to a greater extent zinc, are commonplace at these rural health facilities. Analysis of recent Health Metrics and Evaluation (IHME) data (IHME, 2015) from Zambia found that 26% of rural

health facilities (RHFs) surveyed (n=432) reported having stock-outs of ORS within the previous year, while 32% reported having zinc stock outs. Nationally, 13% of RHFs surveyed were stocked out of ORS on the day of visit, while 55% were out of zinc. Data from the Essential Medicines Logistics Improvement Program (EMLIP) analyzed public sector stock for ORS and zinc in our intervention district of Kalomo (JSI, 2013). They found that during our trial, ORS stock–outs varied from a high of 78% of facilities in November 2012 to a low of 11% of facilities stocked-out in April 2013. The period average was 35% of facilities stocked-out of ORS. With regard to zinc, none was supplied to Kalomo health centers from August - November 2012, or from April –June 2013. Even when zinc is available at health centers, negligible utilization rates would indicate healthcare workers rarely prescribe it.

With only an estimated 59 retail pharmacies throughout the country concentrated in urban centers (40 of which are in Lusaka), and a small number of informal drug shops, there is very limited access to ORS or zinc through the private sector in rural parts of the country (Ballou Aares *et al.*, 2008). However, the over-the-counter (OTC) status afforded to these essential medicines in Zambia would allow them to be sold through private sector, community-level, general stores closer to the household level (Ramchandani, Paper 3).

Few studies have been conducted to facilitate comparison of alternative delivery strategies for ORS and zinc uptake, and countries have few tangible examples around which they can build programs (Fischer-Walker, 2009). Regardless, the provision of low-osmolarity ORS and zinc through public sector clinics alone has not been an effective or lasting strategy in any country (Fischer-Walker, 2009). Incorporating the private sector to strengthen supply chains (Gill,

2013; Fischer-Walker, 2009), and calls to learn from the private commercial sector specifically (Yadav, 2015; Ballou-Aares *et al.,* 2008), have been suggested as promising ways of reaching additional segments of the population. Market-based solutions that simultaneously stimulate both supply and demand of these essential commodities, while supporting manufacturers and distributors, may help facilitate widespread availability (Gill *et al., 2013*). These ideas are central to the theory behind value-chains.

While the concept of value-chains for healthcare delivery has been detailed elsewhere (Porter & Teisberg, 2006; Burns, 2002; Kim *et al.*, 2013), it is worth discussing some of their key features here. The primary focus of value-chains is on the benefits that accrue to end users, the interdependent processes that generate value, and the resulting demand and flow of funds created (Feller et al., 2006). Value is generated when needs of the end user are met through provision of products or services, typically in the form of an exchange or transaction (Feller *et al*., 2006). Thus, value-chains result in collaborative partnerships between networked players engaged in economic exchange (Burns, 2002). Under this scenario, customers at the end of the value-chain, perceiving a product as having value, "pull product" to them. This generates both information for demand planning as well as "value", which both flow back from the customer toward the manufacturer. This strengthens the chain and builds confidence of the players involved, while the product is "pulled" to the end user. This means two things: that end users need to value the product (i.e. in a marketing sense); and they need to have 'value' in their hands to purchase the product (in an economic sense). In this way, effective value-chains generate profit (Feller *et al.*, 2006). Where cash availability is low, 'value' can be placed in the hands of end-users

through distribution of vouchers in order to stimulate, sustain and/or target the value-chain for particular populations. A systematic review of studies on voucher distribution for free or subsidized health goods found that health voucher programs have been successful in increasing utilization of health goods/services, targeting specific populations, and improving the quality of services (Meyer *et al.*, 2011).

Alternatively, traditional supply chain management as seen in most public health systems, starts with the manufacturer and "pushes product" out, toward the end-user (Burns LR, 2002). Push systems are typically designed to work in instances where ordering and stock management capabilities at the lowest level of the distribution system are extremely weak (Yadav *et al.,* 2011). This is a key difference between value-chains and supply-chains – they flow in opposite directions (Feller *et al.,* 2006). Nonetheless, they represent complementary views of an extended enterprise with integrated business processes, which enable the flows of product in one direction, while value, as represented in terms of rapidly shifting tastes, preferences, demand, and cash-flow, moves in the opposite direction (Tan & Zailani, 2009). In this way, the success of the supply-chain depends on the product and the value generated, and vice-versa (Gokhan *et al.*, 2014). This type of systems perspective that uses customer, marketing and management requirements for product design, as well as information relating to suppliers and the value-chain as a whole, has the potential to transform the way we think about access to many public health products.

While value-chain principles have commonly been applied to a multitude of commercial, fast-moving consumer goods (FMCGs), they have typically not been applied to access for essential public health products. FMCGs usually refer to non-

durable products. Examples include beverages such as colas and juices, toiletries such as soap and toothpaste, and grocery items such as sugar and salt. From a consumer perspective, FMCGs are purchased frequently, are typically found to command high levels of brand loyalty, and are usually low-priced (Majumdar, 2004). They move in high volumes, command low margins, and consumers usually spend minimal effort in procuring them (Majumdar, 2004). Most importantly, the shelves of rural, community-level, commercial general stores in LMICs seem to be consistently full of them. We hypothesized that emulating the commercial, private-sector value-chains of fast moving consumer goods (FMCGs), and applying lessons to the introduction of an innovative diarrhea treatment kit, would increase coverage of ORS and zinc at the community-level. Through a public-private partnership with a local pharmaceutical manufacturer and SAB Miller, The Coca-Cola Company's (TCCC) bottling partner in Zambia, and a range of local and international stakeholders, we emulated value-chain principals used by Coca-Cola. This included tapping into the same distribution channels that make FMCGs available in rural Zambian communities. The purpose of this study was to test the impact of this approach on uptake of ORS and zinc.

Methods

Study Design

We tested our hypothesis using a quasi-experimental pretest-posttest design with matched comparators. The study was conducted across four, predominantly agrarian, rural districts of Zambia. Two districts served as intervention arms (Kalomo and Katete), and two served as comparators (Monze and Petauke). Each

intervention district had its own matched comparator (Kalomo with Monze in Southern Province, and Katete with Petauke in Eastern Province), giving two sets of intervention and comparator arms. Intervention districts were purposively selected based on a number of key criteria including being rural (i.e. distance from major centers), presence of mobile phone coverage, high diarrhea rates, logistical considerations (e.g. within a days drive of Lusaka), and the presence of a Coca-Cola/SAB Miller wholesaler. Through a public-private partnership, SAB Miller provided a list of their key wholesalers across the country and agreed to facilitate introductions to those who aligned with our other selection criteria. As with Coca-Cola, these wholesalers served as the sole district-level suppliers of the innovative diarrhea treatment kit introduced through the program. Thus, the intervention occurred at the district level in Kalomo and Katete. This helped to minimize external effects and cross-contamination with respect to ORS and zinc access.

Comparators

The two matched comparator districts – Monze and Petauke - did not receive the intervention and had status quo access to diarrhea treatment through public sector RHCs alone. Intervention and comparator districts were matched on a number of relevant criteria including being rural (i.e. distance from major centers), livelihoods (predominantly agrarian), language/tribe (Tonga in Southern Province; Chewa-Nyanja in Eastern Province), road intensity, diarrhea burden in children under 5, education levels, age distribution of caregivers, combination therapy coverage levels, and substantial consultation with local partners (e.g. UNICEF

Zambia, Keepers Zambia Foundation) who deemed them to be the best possible comparators for each respective intervention district.

Intervention

An end-to-end value chain was established in order to ensure a newly developed, co-packaged ORS and zinc commodity would be available via usual channels for FMCG, at the community level, in the two intervention districts. The ORS and zinc commodity was developed using a human-centered design approach and is covered in more detail elsewhere (Ramchandani, Paper 2). Pre-packaged as Kit Yamoyo®, the diarrhea treatment kit became available through independent, commercial, general retail shops across rural parts of the intervention districts. These retailers are described in more detail elsewhere (Ramchandani, Paper 3), and made up the final link in the value-chain before the product was sold to end-users.

Distribution of the kit occurred via the same secondary channels that bring Coca-Cola and other FMCGs to outlying communities. This market eco-system consisted of existing networks of independent wholesalers (one per district town) and independent, general retailers (i.e. village shops) operating at the community-level across the 'last-mile' (Figure 2.1). Kits were transported from the pharmaceutical manufacturer in Lusaka to district level wholesalers by Medical Stores Limited (MSL), the same parastatal responsible for distributing drugs and other commodities to the district level for the public sector. The manufacturer's price, including delivery to wholesaler was 3100 Kwacha (~US 57 cents[ii]) per kit. The wholesale price to retailers was 3700 Kwacha (~US 69 cents). And the retail

[ii] At prevailing 2012-2013 exchange rate

price for caregivers was 5000 Kwacha (~US 93 cents). In this way, the manufacturer, wholesalers, and retailers all benefited from a profit incentive.

The kit was subsidized at the top-end of the value-chain (manufacturer level) during the trial, but with a view to becoming commercially sustainable post-trial. A breakdown of the kit's costing during the trial, and since, is provided in Appendix 3. The retail price of 5000 Kwacha was established based on willingness-to-pay studies (IDinsight, 2013) and in consultation with caregivers, and then the kit's value-chain was reverse engineered to ensure that a retail price at this level could sustain a profitable value-chain (i.e. price-minus-costing approach).

In addition to developing a demand-driven product and engaging with the existing market eco-system for FMCGs, establishment of the value-chain also consisted of demand-generation activities. A social marketing campaign involving a cadre of community promoters, vouchers, radio spots, posters, liaison with RHCs and retailer training/para-skilling formed a core third component of the approach. In most cases, promoters were community health workers (CHWs) whose training through the Ministry of Health relating to product benefits (including those of ORS and zinc), as well as proper diarrhea treatment seeking behaviors more generally, were reinforced. Product-specific training was also provided.

Approximately 30 promoters per intervention district ran awareness campaigns and demonstrations at the community-level. Methods such as drama and testimonials from previous kit-users were used, usually during existing health-related events including child health days. Content included the definition of diarrhea, common signs and stages of dehydration, indications for referral, benefits of ORS and zinc, as well as hand-washing and other preventive behaviors. While the

OTC product was designed to be self-sufficient, not requiring any attached service, retailers were also trained on similar content. Finally, radio spots (including a Kit Yamoyo jingle) covered similar material.

The vouchers provided by promoters as part of the demand generation strategy covered the full value of the kits (figure 2.2). While they were only distributed during the first six months of the trial, they were redeemable throughout the pilot period. A total of 28,000 vouchers were distributed. Vouchers were used as a product launch and market preparation tool. They allowed caregivers to access kits at no cost from community-level retailers, and were implemented in order to catalyze rural market demand in a short period of time. In other words, they put 'value' in the hands of caregivers and helped create the "pull" required to trigger the value-chain. They could be exchanged for a kit by caregivers at the retailer level. Retailers were able to redeem the vouchers for the full value of the kit using their mobile phones (mobile money transfer) or by visiting the project office in the district town. They were required to purchase the kits from wholesalers. Kits were also available to caregivers for cash purchase throughout the study period.

Trial End Point

The highest-level outcome of the trial relates to coverage of ORS and zinc combination therapy. Coverage is defined as the proportion of children under age five with diarrhea in the previous two weeks who received zinc with ORS (DPWG, 2014). Diarrhea was defined as experiencing three or more loose or watery stools during the previous 24 hours. Given that baseline figures for zinc use were less than

1%, we compared the difference in coverage proportions between each set of intervention and comparator arm at endline only. Use of ORS and zinc was operationalized based on the caregiver reporting that the child suffering from diarrhoea received both ORS and zinc. As defined, utilization was not necessarily based on effective/rational use, but any use at all. This is in line with global reporting standards. For example, if the child received any amount of zinc (not necessarily the full ten-day course), they were counted as having received zinc. The end point was measured in a representative cross-sectional household survey conducted after program implementation. We also examined the difference in total ORS coverage (i.e. with or without zinc) between intervention and comparator districts at baseline and endline.

Study Population, Sampling and Household Surveys

Representative households surveys were administered to independent, cross-sectional samples of primary caregivers of children under-5 (the vast majority being mothers) from rural communities of Southern and Eastern Province, Zambia. Surveys were conducted at baseline in August of 2012, prior to the intervention, and at endline in August of 2013, after exactly one year of implementation.

In each district, households were sampled from 12-15 rural sites. Sites were defined by the presence of a community-level retailer (or a cluster of retailers) at the center, and their 5 Km radius (A = 78.5km$^{2)}$. Retailers were identified during a pre-study survey that attempted to identify all retailers in the district (Ramchandani, Paper 3), as there was otherwise no accurate record of rural retailers or their locations. Identification of retailers was carried out in consultation

with key stakeholders including the District Planner in each district. This resulted in good geographic coverage of populated areas across the entire district (Figure 2.3), helping to reduce the potential for selection bias. The majority of identified retailers was recruited into the study, trained in product benefits and issues around diarrhea, and became Kit Yamoyo outlets after the baseline. Parts of the district within 10km of town ("urban centers") were excluded. As a result, the baseline and endline samples were specifically representative of the rural population within the rural study districts.

No information on the specific locations of households was available during the survey periods. Households were, therefore, selected using a modified random-walk technique with probability proportional to population size within the site [based on Standard Enumeration Area (SEA) data from the Central Statistics Office (CSO)] (Turner, 2003). A sampling interval of 3 was used to determine each successive household, after randomly selecting the first household along the perimeter of the site. Due to large distances between households in Southern Province, the interval was altered to 1 or 2 (where necessary). An interval of 3 was selected to avoid any potential clustering effects and selection bias, but was likely unnecessary given the large distances between some households in Southern Province.

The primary caregivers selected for interview had to be at least 15 years of age. In those instances where there were multiple primary caregivers of children under-5 residing within a household, those who had a child with diarrhea in the previous 2 weeks were prioritized. If there were multiple caregivers that met these selection criteria, the caregiver sampled was selected alphabetically by first name.

The same sampling procedure was used in instances where the selected caregiver had multiple children under 5 with diarrhea in the two weeks preceding the survey. Only using a single reference child per household eliminated intra-household correlation. A two-week period was used in order to minimize recall bias and ensure comparability by aligning with the globally recognized indicator for coverage.

Local enumerators from an external data collection agency, with previous survey experience, were trained by the project and administered all surveys (professionally translated) in the local language. Surveys typically took between 20 and 60 minutes to complete, and were carried out over the course of three weeks. All surveys were carried out on Samsung tablets using Open Data Kit (ODK). Consistency checks and skips to avoid entry of erroneous data were automated in the electronic surveys. All data was crosschecked by trained field supervisors on a daily basis and then uploaded to a central server each evening. Uploaded data was then checked by a data specialist from the data collection agency for completeness and consistency, as well as coding of open-ended responses. In cases of inconsistency, missing responses, or other questions, the data specialist flagged them for discussion with supervisors and the principal investigator for any necessary follow-up with interviewers. Surveys measured the prevalence and treatment of diarrhea, demographic characteristics, as well as factors related to diarrhea treatment seeking by caregivers and use in children under-5. The questionnaire adapted and built upon the Toolkit for the Collection of Survey Data on the Correct Use of Pediatric Zinc as a Treatment for Diarrhea (MacDonald & Banke, 2011), developed for the USAID SHOPS project in consultation with leading experts.

Sample Size and Statistical Analysis

The primary analysis of this study aimed to test whether emulating the commercial, private-sector value-chains of FMCGs like Coca-Cola, and applying lessons to the introduction of an innovative diarrhea treatment kit, would increase coverage of ORS and zinc in children under-5 with diarrhea. Secondary analysis looked at the effect of the intervention on total ORS coverage (with or without zinc). Given that there was no baseline information on zinc coverage (anecdotally it was known to be very low), an a priori sample size estimation was made prior to baseline in order to provide 80% power to detect a 20% difference in *ORS use alone* with a two-tailed alpha of 0.05. Assuming a 25% period prevalence of diarrhea during the high burden season (DHS, 2007; confirmed to be valid during baseline) and a baseline treatment level of 60% (DHS, 2007), the estimate was 548 households with children under-5 per study arm. This was rounded up to 600 households to account for the potential of a small design effect. Using ORS coverage as the basis for the sample size calculation ensured ample power for detecting a difference in our main outcome - combined use of ORS and zinc.

Given that zinc coverage was <1% at baseline across all districts, evidence of the trial's success or failure was determined by the difference in ORS with zinc coverage between matched intervention and comparator districts at endline. The primary end point was calculated as the proportion of diarrhea cases within the previous two weeks treated with ORS plus zinc among children under-5, computed as a percentage for each district. The effect of the intervention is the difference in percent or 'delta' of ORS plus zinc treatment between each set of intervention and

comparator districts at endline. A pooled analysis was also conducted comparing coverage across both intervention districts vs. both comparator districts. We used a generalized linear model (GLM) with Poisson distribution to estimate relative risk of combined ORS and zinc use (Zou, 2004). Variances of beta coefficients are adjusted for within site correlation.

In order to assess the impact of the program on total ORS coverage (with or without zinc), additional analysis compared pre and post-intervention levels of total ORS use using a difference-in-differences (DiD) analysis. Logistic regression with time (pre- vs. post-intervention), study arm (intervention vs. comparator) and their interaction was used to assess the odds ratios for total ORS use comparing intervention vs. comparator districts. The Wald test for the interaction term from this model shows whether there is a statistically significant difference between odds ratios in the intervention versus comparator districts (i.e. DiD analysis). A robust variance estimate was used to account for within-site correlation of outcomes (Gutierrez R & Drukker D.M., 2007).

In addition, we present the DiD estimator for each set of intervention and comparator district, as well as a pooled analysis which compares outcomes across both intervention districts combined and both comparator districts combined. DiD estimation provides evidence of program effectiveness by comparing the changes in outcomes between baseline and endline in the intervention and comparison districts (Gertler et al., 2011). It can be used with quasi-experimental designs by analyzing independent cross-sections across time and using the change in outcomes for the comparison district as an appropriate counterfactual for the intervention district (Wooldridge JM, 2009). This quasi-experimental setup permits isolation of

the effect of the overall approach by applying a DiD estimator. These estimators are categorized as within estimators because they rely on the assumption that any potential unobserved confounders are fixed with respect to time and identify impact based on variation in outcomes and exposure over time (Lance *et al.,* 2014*)*. One of the key advantages of the DID approach is that baseline characteristics, including levels of the outcome of interest, do not need to be comparable at baseline, as the method compares differences over time in the treatment group to those in the comparator (Buckley & Shang, 2003).

Data on key social and demographic characteristics are also presented that show comparability of intervention and comparator districts over time (baseline vs. endline). All analyses were conducted using STATA version 13 (StataCorp, 2013).

Ethical Approval and Consent

Informed consent was obtained from all respondents prior to survey administration. In cases where the caregiver was under the age of majority, consent was sought from both the head of household and the caregiver themselves. Because this was a low-literacy population, the statement of consent was explained to the caregivers, who then provided signature (if possible) or made their mark using their finger and ink. Both national and district level government health administrations authorized the implementation of the study while community-level approval was obtained through local chiefs. Ethical approval for the study protocol was obtained from ERES Converge in Zambia, with approval for secondary analysis obtained through Johns Hopkins School of Public Health Institutional Review Board.

Results

A total of 2458 and 2477 households with children under age 5 were successfully surveyed across all four districts at baseline and endline, respectively. The survey verified comparability between intervention and comparator districts at baseline, with reference to a number of key variables related to diarrhea treatment including age and education of caregivers, perceived seriousness of diarrhea as a health concern for children under-5 at the community level, proportion of public sector access of ORS, household period prevalence in children under 5, and use of recommended treatments (Table 2.1). Almost all ORS access was from public sector sources in all districts. Use of zinc with ORS was less than 1% in all districts at baseline. While there was a statistically significant higher level of ORS use (with or without zinc) in Monze (62.9%) as opposed to Kalomo (48.7%) (p=0.007) prior to the intervention, the DiD approach used to assess the effect of the intervention on total ORS coverage in the second analysis accounts for this.

Table 2.2 shows the difference between intervention and comparator districts at endline with regard to household prevalence of diarrhea, coverage levels of recommended treatments, and the proportion of caregivers who sourced ORS from the public sector. All other characteristics presented in Table 2.1 saw no significant change, except for mean distance to an ORS access point. Due to the shift in point of access from the public to the private sector (as demonstrated by the proportion of caregivers who obtained ORS from the public sector), the mean distance to access ORS decreased for those using Kit Yamoyo. This will be discussed further in a future paper.

With regard to point of access for ORS, there was a clear shift to the private sector, and specifically to use of Kit Yamoyo. The proportion of ORS users who obtained ORS from the public sector fell from close to 100% (Table 2.1) to 40.1% in Kalomo and 34.1% in Katete, while ORS continued to be sourced solely from the public sector in both comparator districts. This represents a significant shift from the public to private sector in the intervention districts of 60% in Kalomo and 56% in Katete. A decrease from baseline was seen in household prevalence of diarrhea across all districts as well, however there was no significant difference between the paired intervention and comparator districts.

With regard to the primary analysis, there was a significant difference in the use of zinc with ORS at endline when comparing intervention and comparator districts. Both intervention districts saw significant increases in combination therapy use, to 46.9% in Kalomo and 46.3% in Katete, while utilization in comparator districts remained very low and similar to baseline levels (Table 2.2; Figure 2.4): 1.7% in Monze and 0.6% in Petauke. The unadjusted risk ratio for utilization of ORS with zinc comparing Kalomo to Monze was 27.0 (95% CI: 10.6-69.1, $p<0.001$). The unadjusted risk ratio for utilization of ORS with zinc comparing Katete to Petauke was 75.2 (95% CI: 10.3-547.7, $p<0.001$). We also conducted a pooled analysis comparing intervention and comparator districts combined. The unadjusted risk ratio for utilization of ORS with zinc comparing the intervention districts to the comparators was 39.0 (95% CI: 13.2-115.2, $p<0.001$) (Table 2.3).

The secondary analysis used a DiD approach to compare the change in total ORS use (with or without zinc) between baseline and endline in the intervention vs. comparison districts. Table 2.4 summarizes the difference-in-differences analysis

and shows the proportion of under-5 children who were given ORS in each district at both baseline and endline. It shows the differences between each set of matched intervention and comparator at pre and post periods, and provides the DiD estimator.

The analysis indicates that the intervention was associated with a significant overall increase (i.e. from all sources) in use of ORS in the intervention district of Kalomo as compared to its comparator Monze, with a DID estimator of 40 ($p<0.001$). Table 2.5 shows the odds of ORS use were 3.67 times higher (95% CI: 1.77-7.61, $p<0.001$) in Kalomo than in Monze at endline, while they were significantly lower at baseline (OR=0.56, 95% CI: 0.37-0.85, p=0.006). The Wald test for the interaction term (time by study-arm) from this model (Table 2.5) verifies the significance of the estimator in table 2.4, and shows that there was a significant difference between the odds ratios in Kalomo vs. in Monze.

With reference to the second intervention district and its comparator, the difference in differences analysis found a non-significant DiD estimator of 8.2 (p=0.178) (Table 2.4). The odds of ORS use were not significantly different in Katete compared to Petauke at either baseline (OR=1.06; 95% CI: 0.74-1.52; p=0.749) nor at endline (OR=1.57; 95% CI: 0.78-3.15; p=0.208), with the proportion of ORS use staying relatively the same in Katete and dropping non-significantly in Petauke. ORS use was already relatively high at baseline in these districts and no major increase in ORS use was hypothesized, rather only a shift in point of access and toward use of the combination therapy.

The overall pooled analysis comparing both intervention districts to both comparators shows a significant change in ORS use over time across the

intervention districts. Here too, the DiD estimator of 24.8 ($p<0.001$), is verified by the significance of the Wald test for the interaction term in this model ($p<0.001$) (Table 2.5).

Within each district, the odds of ORS use comparing baseline to endline were only significantly greater in Kalomo post intervention (OR=4.71, 95% CI: 2.68-8.26, $p<0.001$), while the odds of use remained similar in Katete (OR=1.07, 95% CI: 0.65-1.78, $p=0.787$), and decreased non-significantly in both comparators (Table 2.5).

Programmatic data recorded approximately 26,000 Kit Yamoyo anti-diarrhea kits being sold by wholesalers to community-level retailers in the intervention districts over the one-year trial period. A breakdown of sales (voucher and cash-based sales combined) from wholesaler to community-based retailers is provided in Appendix 4.

Discussion

The application of business principles to global health is an evolving science. Our trial provides evidence that emulating the commercial, private-sector value-chains of fast moving consumer goods (FMCGs), and applying lessons to the introduction of an innovative diarrhea treatment kit can result in a significant increase in coverage of ORS and zinc at the community-level. After a one-year study period, the coverage of this globally recommended combination therapy was several-fold higher in the intervention districts compared with the matched comparators at endline. The use of ORS (with or without zinc) was also found to be significantly higher in the intervention district of Kalomo after implementation, while it remained relatively stable in the intervention district of Katete, and reduced

non-significantly in the comparators. However, there was a significant shift in the source of the ORS used in the intervention districts from public to private sector.

Additional findings reinforce and strengthen the plausibility that the intervention was responsible for the increase in proper treatment of childhood diarrhea. Use of zinc with ORS at baseline was less than 1% in both intervention and comparator districts. Use of this combination therapy increased significantly to ~46% in both intervention districts relative to baseline, while coverage levels in both comparators remained relatively the same at negligible levels. At baseline, both sets of intervention and comparators were similar with reference to factors that may have influenced the outcome of the intervention, including caregiver age, education, perceived seriousness of diarrhea as a health concern for children under-5, where they would typically access ORS, reported distance to a treatment access point, and period prevalence. Programmatic data also indicated that the amount of ORS and zinc delivered to the community level was commensurate with the observed effect size. This was also reflected in a shift in treatment source at endline (i.e. to the private sector), which corresponds to the coverage with Kit Yamoyo. There was no other source of zinc in the private sector throughout the trial period in project districts, and no other diarrhea-focused programs were active during the trial in any of the districts, other than the standard rural health center services. The latter was confirmed with District Medical Officers (DMO) in each district and through regular monitoring through a multi-organizational Steering Committee (i.e. those with interest in diarrhea treatment) chaired by the Ministry of Health.

At its core, establishment of the value-chain for the Kit Yamoyo had three core pillars, including:

1. Development of a public health commodity, based on human-centered design (Ramchandani, Paper 2), concurrently with its supply-chain (i.e. simultaneous consideration of both supply and demand elements of access).

2. Tapping into existing, local networks of private sector actors, including local manufacturers, district-level wholesalers and community-level, commercial, general retailers (Ramchandani, Paper 3) who made a profit from selling the product.

3. Demand generation activities beyond the design of the product, including social marketing (radio, posters, community events, drama, testimonials, etc.), working with rural health centers including CHWs, training of retailers and reinforcement of training for promoters (i.e. often CHWs), and targeted distribution of vouchers (i.e. for the total value of the product).

These were enabled by drawing on the best expertise and establishing partnerships across organizations and sectors to generate maximum value. In this way, the value-chain concept inherently addresses the core barriers identified for reducing childhood deaths from diarrhea - access, production, distribution and promotion - by taking a systems approach (Gill et al., 2013).

While the study design could not disaggregate which component of the model contributed the most to increased uptake, and which stand to be improved or removed altogether, this type of "package of interventions" has a theoretical basis for being stronger than its component parts (Montagu D, 2002). Future research will attempt to disaggregate which components are necessary and which are sufficient. This, for example, might include comparing and contrasting the most cost-effective methods for generating (and sustaining) demand for a newly introduced health commodity into rural markets (e.g. vouchers vs. other mechanisms). However lending strength to previous recommendations (Gill et al., 2013), it is clear that simultaneous stimulation of supply and demand with coordinated marketing

campaigns, while supporting manufacturers and distributors, can indeed help to ensure widespread availability and use.

Existing networks of private sector players (e.g. wholesalers, community-level retailers) can be leveraged and trained to provide access to basic health commodities at the community level. These secondary distribution channels, beyond the district towns, already exist and can help overcome distribution bottlenecks seen in the public sector. In the trial we contracted with Medical Stores Limited (MSL) on commercial terms to distribute the product to the district level. This function could have been fulfilled by one of many pharmaceutical distributors that operate between Lusaka and the district towns where the wholesalers were located.

Introducing these complementary points of access to the public sector can serve to improve community case management of diarrhea at the household level. However, in order to assess progress/success in management of diarrhea, there is a need to go beyond ORS and zinc coverage data. Additional research is needed around the detailed and rational use of ORS and zinc at the household level. This would include factors such as whether ORS is prepared in the correct concentration (Ramchandani, Paper 2), whether it is consumed within the recommended 24 hour period, whether it is prepared with treated water, as well as the level of adherence to the 10-day zinc regimen. This should be considered an important part of the implementation and delivery science research agenda. In the same vein, other seemingly important elements of the model should be evaluated from a process perspective. With obvious implications for feasibility and sustainability, these include the quality of information/services provided by general, commercial

retailers, the role of project management/champions in catalyzing the value-chain, as well as consideration of enabling factors. Enabling factors that facilitated effectiveness of the value-chain intervention for Kit Yamoyo included such things as over-the-counter status of zinc, support of private-sector initiatives by national authorities, international recognition through awards and social media, and cooperation and capacity of local private sector manufacturers (especially if local production of products are emphasized). Gaining greater insight into the role such factors play in contributing to overall value of this type of 'total-market approach' will be important for future adaptations.

Limitations

Limitations to the study are noted. For example, vouchers were distributed during the first half of the trial and caregivers were able to access kits at no cost while the value-chain was being established and fortified. Of the 26,000 kits sold, ~21,000 were purchased with vouchers and ~5,000 with cash. Further research would be required to assess a market-driven approach without voucher-based incentives.

Producers of FMCGs, such as Coca-Cola, commonly use vouchers and other promotional methods to stimulate market demand. Vouchers helped provide retailers with the confidence to purchase the new kits from wholesalers and bring them into their communities. It also allowed caregivers to try a new product without having to pay for it. In addition, the perceived commercial risk associated with entering the market for often low-cost public health products can deter potential manufacturers. Vouchers can effectively be used to entice new entrants by building

market demand and allowing the product to gain traction. Vouchers do this without distorting the value-chain. Rather, they strengthen it by putting value in the hands of the customer. This has the effect of strengthening existing distribution systems rather than undermining them. Public funds can be impactful in facilitating these types of market-shaping initiatives, as well as the associated research and development that is necessary, prior to transferring full ownership of the value-chain over to the private sector for long-term sustainability. Our objective was to test whether emulating the value-chains of FMCGs, and applying the lessons to a diarrhea treatment kit would increase coverage of ORS and zinc. We were successful in this endeavor.

While a cluster randomized trial would be considered the gold standard design for such a trial, random allocation of the districts to intervention or comparator was deemed to be in contention with the free market aspects of the value-chain we were attempting to test. As such, the selection of districts for the study was purposeful and therefore may not be completely representative of all rural areas of the country, however, as in any business transaction, the willingness, interest, accountability and level of engagement of the independent, private wholesalers all play an important role. While this has implications for external validity, it would inevitably be an important consideration in any potential scale-up scenario. In addition, with only two intervention districts and two comparator districts, randomly allocating the intervention would have added little statistical advantage and claiming true randomization would have been somewhat arbitrary. With an ever-expanding focus on health market interventions (i.e. inherently not

congruent with control), the feasibility and appropriateness of RCTs for assessing these types of interventions should be considered.

Intensity of promotion differed by intervention district. In the six-month period from April to September of 2013, 1195 events were conducted by promoters, of which 68% were in Kalomo and 32% were in Katete (this programmatic output-level data was not gathered prior to April 2013). While Katete started out stronger, in the long run, Kalomo field staff ended up being more effective both in terms of messaging and post-March 2013 sales (Appendix 4), after voucher distribution stopped. This may account for some of the variability in effect seen in the two intervention districts, particularly with regard to ORS use with or without zinc, which increased in Kalomo while remaining relatively constant in Katete.

While an impact on household prevalence of diarrhea was not hypothesized for this one-year intervention, a drop was found across all four districts (Table 2.1 & 2.2). Within each district, household prevalence decreased significantly from baseline to endline in both of the intervention districts of Kalomo (OR: 0.68, p=0.001) and Katete (OR: 0.69; p=0.002), as well as in Petauke (OR: 0.45; p<0.001). It did not decrease significantly in Monze (OR: 0.86; p=0.238). Given that drops in prevalence were seen in both intervention districts, as well as in comparators (the largest taking place in Petauke), it is unlikely that the observed difference was due to the intervention. Although some decrease in the intervention districts may be possible due to the short-term protective effect (from re-infection) conferred by zinc, given the drop seen across all districts, it is more likely attributable to seasonal shifts which can occur from one year to the next. Baseline data collection took place during a particularly dry August during which many communities were facing

drought. Studies focused on sub-Saharan Africa have demonstrated that when water is scarce the prevalence of diarrhoea (non-cholera) increases due to consumption of unsafe water and poorer hygiene practices (Bandyopadhyay *et al*., 2011; Fewtrell et al. 2005). This may be one possible explanation for the difference in household prevalence between August of 2012 and 2013.

Our intervention proved feasible in multiple rural communities in two distinct geographic areas (Southern and Eastern Provinces) of Zambia. Given that a large proportion of the country is rural, we project that gains observed in our study could translate to subnational reductions in childhood morbidity and mortality, particularly if efforts are made to increase and sustain uptake. Previous research has also demonstrated that optimal treatment with ORS and zinc, as facilitated by our innovative kit design (Ramchandani, Paper 2), is associated with reductions in inappropriate use of antibiotics and intravenous fluids for diarrhea (Habib, 2013; Das, 2013; Fischer Walker et al, 2011; Borapich et al, 2010; Santosham et al, 2010). Estimates have shown that if the combination therapy of ORS and zinc achieved universal coverage, 75% of diarrheal deaths could be averted (Gill 2013, Jones 2003), which in 2013 would have reduced overall childhood mortality by 7%.

Implementation of a value-chain approach for over-the-counter public health products, like a diarrhea treatment kit, can significantly improve coverage at the community level. Aside from measuring the impact of a market-based intervention on a priority child health outcome, this study will help inform future interventions and policy initiatives for this priority childhood disease. Ensuring community-level access of ORS and zinc within multiple sectors of the health system will contribute to achieving universal health coverage and in reducing global childhood mortality.

Figures for Chapter 2

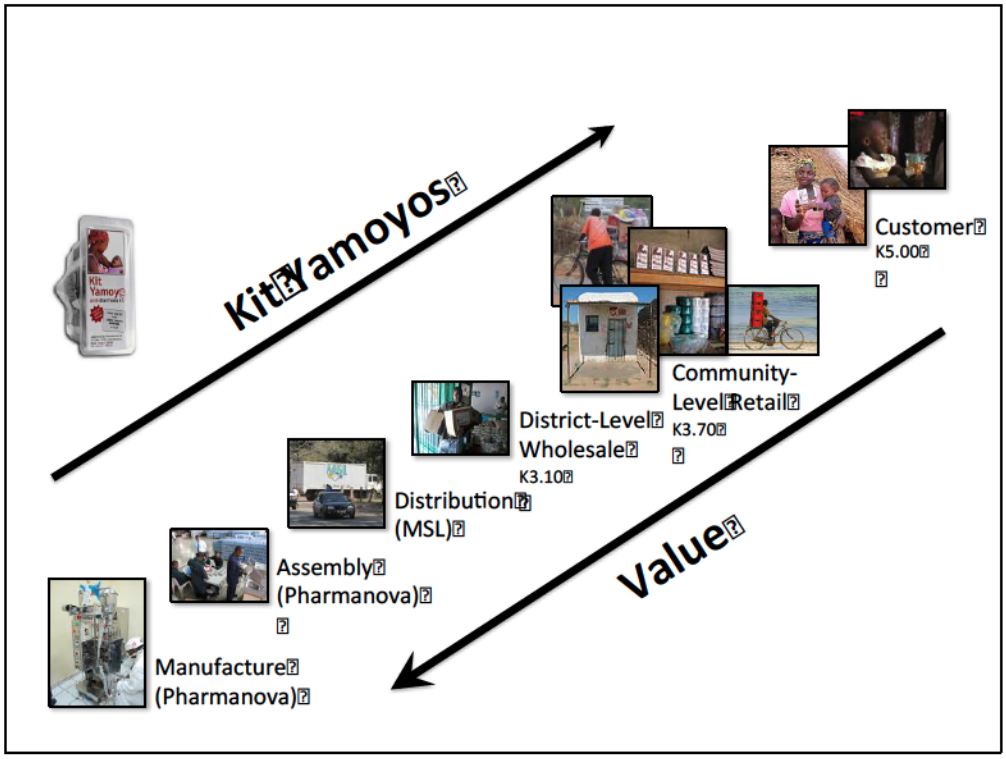

FIGURE 2:1: THE KIT YAMOYO VALUE-CHAIN ***(SOURCE: COLALIFE)***

FIGURE 2:2: KIT YAMOYO VOUCHER

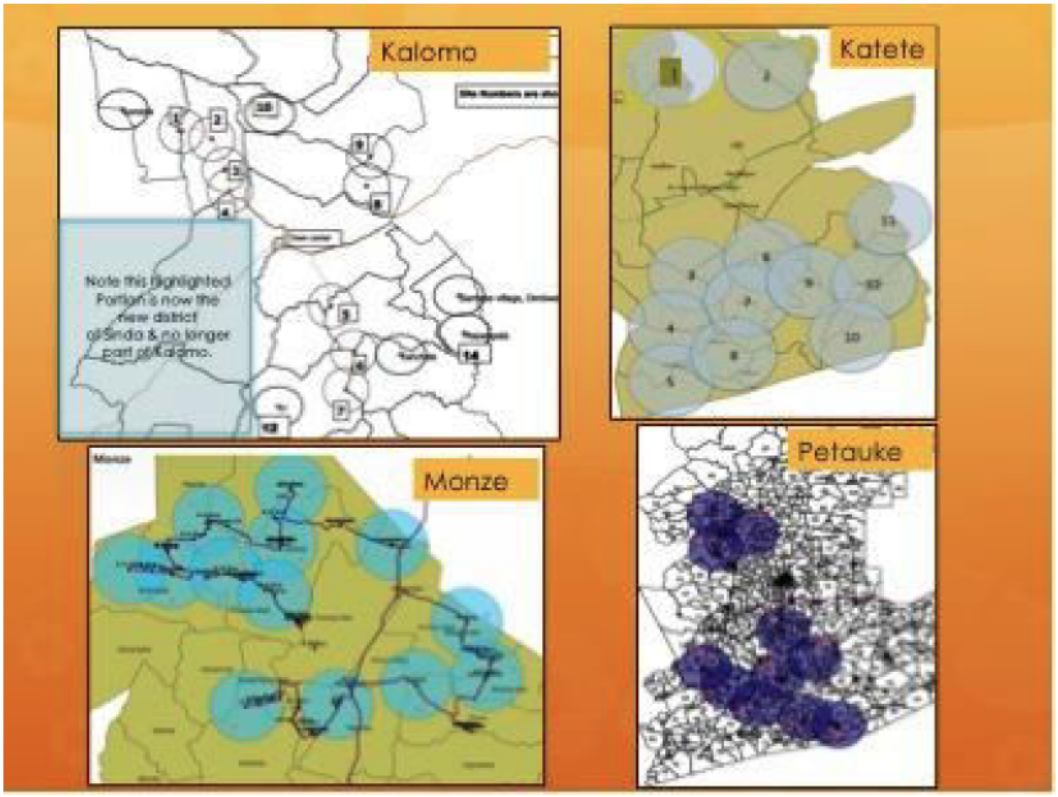

FIGURE 2:3: STUDY DISTRICTS AND SITE MAPS

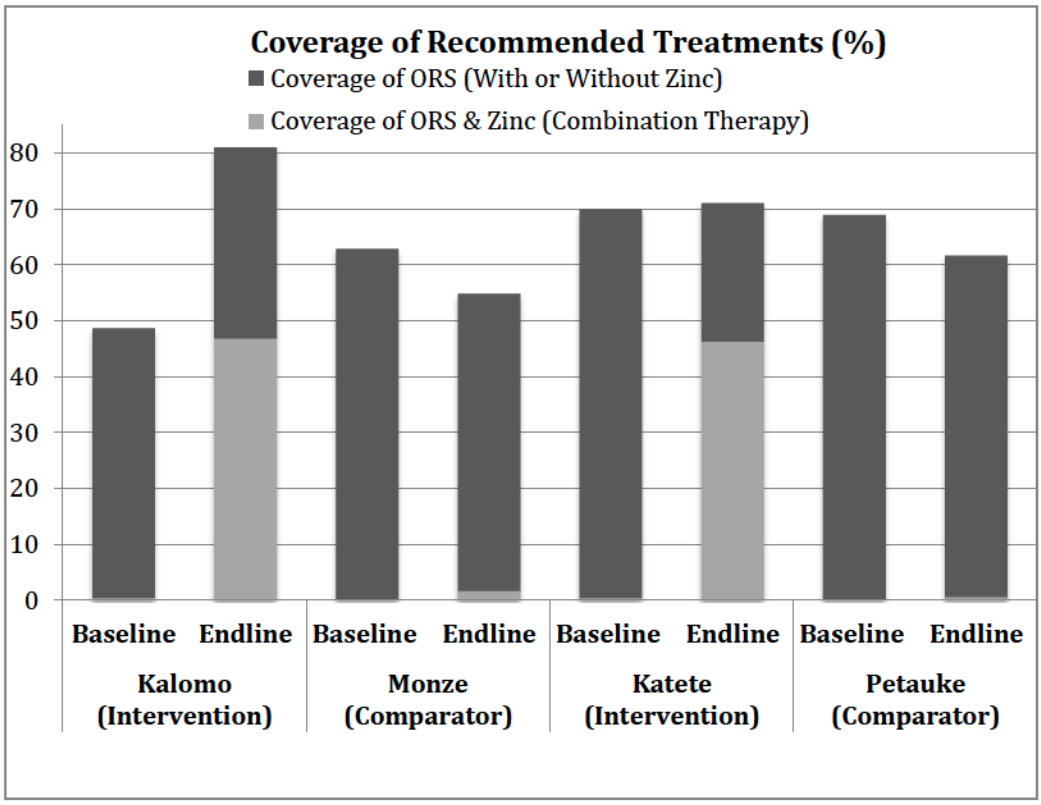

FIGURE 2:4 COVERAGE OF RECOMMENDED TREATMENTS, BASELINE VS. ENDLINE, INTERVENTION VS. COMPARATORS

Tables for Chapter 2

TABLE 2.1: CHARACTERISTICS OF INTERVENTION (KALOMO & KATETE) AND COMPARATOR DISTRICTS (MONZE & PETAUKE, RESPECTIVELY), 2012

Characteristic	Southern Province			Eastern Province		
	Kalomo (Intervention) N=620	**Monze** (Control) N=611	p-value*	**Katete** (Intervention) N=623	**Petauke** (Contol) N=604	p-value*
Mean Age of Respondent Caregiver	30 SD: 10.1 n=619	30 SD: 9.9 n=610	0.439	29 SD: 8.2 n=611	29 SD: 8.8 n=587	0.569
Caregiver has above primary education (%)	12.9 SD=33.6 n=619	14.5 SD=35.2 n=608	0.540	4.0 SD=19.7 n=622	4.8 SD=21.5 n=600	0.421
Caregivers who cited diarrhea as a main health issue of children under 5 in their community (%)	79.1 SD=40.7 n=620	82.0 SD=38.5 n=611	0.368	81.3 SD=39.0 n=623	79.5 SD=40.4 n=604	0.487
Caregivers who cited public sector as where they typically access ORS (%)	99.4 SD=9.3 n=456	99.7 SD=4.6 n=471	0.207	99.4 SD=7.6 n=514	99.5 SD=6.5 n=469	0.884
Proportion of households with diarrhea in children <5yrs old in previous 2 weeks (%)	37.1 SD=48.3 n=620	31.5 SD=46.6 n=611	0.189	39.3 SD=48.9 n=623	43.2 SD=49.6 n=604	0.100
Proportion of children under 5 with diarrhea who used ORS with Zinc (%)	0.4 SD=6.6 n=230	0 n=194	0.358	0.4 SD=6.4 n=245	0 n=261	0.302
Proportion of children under 5 with diarrhea who used ORS (with or without zinc) (%)	48.7 SD=50.1 n=230	62.9 SD=48.4 n=194	**0.007**	70.2 SD=45.8 n=245	69.0 SD=46.4 n=261	0.749
Mean reported distance to ORS access point (km) by those with a child who had diarrhoea in preceding 2 weeks	8.5 SD=11.7 n=112	5.5 SD=10.5 n=122	0.110	4.9 SD=6.2 n=172	5.5 SD=4.4 n=180	0.479

*p-values are for the unadjusted odds ratio comparing matched districts and account for within site correlation of outcomes for proportions and t-tests for difference in matched districts for means.

TABLE 2.2: COVERAGE IN INTERVENTION (KALOMO & KATETE) VS. COMPARATOR DISTRICTS (MONZE & PETAUKE, RESPECTIVELY) AT ENDLINE, 2013

Characteristic	Southern Province			Eastern Province		
	Kalomo (Intervenion) N=614	**Monze** (Control) N=604	p-value *	**Katete** (Intervention) N=626	**Petauke** (Control) N=633	p-value*
Proportion of households with diarrhea in children <5yrs old in previous 2 weeks (%)	28.5 SD=45.1 n=614	28.6 SD=45.2 n=604	0.967	31.0 SD=46.2 n=626	25.6 SD=43.7 n=633	0.084
ORS with Zinc Use in children <5 With Diarrhoea (%)	46.9 SD=50.0 n=175	1.7 SD=13.1 n=173	**0.000**	46.3 SD=49.9 n=194	0.6 SD=7.9 n=162	**0.000**
ORS Use (%)	81.1 SD=38.8 n=175	54.9 SD=49.9 n=173	**0.000**	71.1 SD=45.2 n=194	61.7 SD=48.8 n=162	0.224
Caregivers with child <5 suffering diarrhea in 2 weeks preceding survey who obtained ORS from public sector (%)	40.1 SD=49.2 n=142	96.8 SD=17.9 n=95	**0.000**	34.1 SD=47.6 n=138	99.0 SD=10 n=100	**0.000**

*p-values are for the unadjusted risk ratio comparing matched districts and account for within site correlation of outcomes for proportions.

TABLE 2.3: RISK RATIO FOR UTILIZING ORS WITH ZINC IN INTERVENTION (KALOMO & KATETE) VS. COMPARATOR DISTRICTS (MONZE & PETAUKE, RESPECTIVELY) AT ENDLINE, 2013

	GLM	
Characteristic	**Risk Ratio (95% CI)** [a]	**p-value**
Kalomo (intervention) vs. Monze (comparator) (n=348)	27.0 (10.6-69.1)	**0.000**
Katete (intervention) vs. Petauke (comparator) (n=356)	75.2 (10.3-547.7)	**0.000**
Intervention vs. Comparator (Pooled)	39.0 (13.2-115.2)	**0.000**

[a]Generalized Linear Model with Poisson distribution to estimate relative risk; Adjused for within site correlation using robust variance estimate

TABLE 2.4: DIFFERENCE IN DIFFERENCES *ANALYSIS FOR EFFECT OF EMULATING PRIVATE SECTOR VALUE-CHAINS ON UTILIZATION OF ORS (WITH OR WITHOUT ZINC), RURAL ZAMBIA, 2012-2013*

	Baseline	Endline	Difference	DID	*p*-value
Intervention (Kalomo)	48.7	81.1	32.4		
Comparator (Monze)	62.9	54.9	-8.0		
Difference	-14.2**	26.2***		40.4	0.000***
Intervention (Katete)	70.2	71.1	0.9		
Comparator (Petauke)	69.0	61.7	-7.3		
Difference	1.2	9.4*		8.2	0.178
Intervention (Pooled)	59.8	76.4	16.6		
Comparator (Pooled)	66.4	58.2	-8.2		
Difference	-6.6*	18.2***		24.8	0.000***

p-values are for the Wald test based on linear regression.
***p <0.001, **p<0.01, *p<0.05

TABLE 2.5: IMPACT OF *EMULATING PRIVATE SECTOR VALUE-CHAINS: DIFFERENCE AND CHANGE IN USE OF ORS AMONG INTERVENTION AND COMPARATOR HOUSEHOLDS, RURAL ZAMBIA, 2012-2013*

Comparison	Odds Ratio (95% Confidence Interval)	*p*-value
Intervention (Kalomo) vs. Comparator (Monze) at Baseline	0.56 (0.37 – 0.85)	**0.006**
Intervention (Kalomo) vs. Comparator (Monze) at Endline	3.67 (1.77-7.61)	**0.000**
Intervention (Kalomo) Endline vs. Baseline	4.71 (2.68-8.26)	**0.000**
Comparator (Monze) Endline vs. Baseline	0.72 (0.43-1.19)	0.200
Time by Study-Arm Interaction	6.55 (2.96-14.49)	**0.000**
Intervention (Katete) vs. Comparator (Petauke) at Baseline	1.06 (0.74-1.52)	0.749
Intervention (Katete) vs. Comparator (Petauke) at Endline	1.57 (0.78-3.15)	0.208
Intervention (Katete) Endline vs. Baseline	1.07 (0.65-1.78)	0.787
Comparator (Petauke) Endline vs. Baseline	0.73 (0.46-1.15)	0.173
Time by Study-Arm Interaction	1.48 (0.69-3.17)	0.317
Pooled Intervention vs. Comparator at Baseline	0.75 (0.57-0.99)	0.049
Pooled Intervention vs. Comparator at Endline	2.33 (1.36-3.98)	0.002
Pooled Intervention (Endline vs. Baseline)	2.17 (1.47-3.24)	0.000
Pooled Comparators (Endline vs. Baseline)	0.71 (0.48-1.04)	0.080
Time by Study-Arm Interaction	3.09 (1.64-5.81)	**0.000**

Adjusted for within site correlation using robust variance estimate

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Chapter 3 - Product Innovation and Human-Centered Design for Global Health Delivery: Improving Effective Use of Oral Rehydration Salts Through the Introduction of an Innovative Diarrhea Treatment Kit

Abstract

A recent focus on affordability and supply has dominated discussions of access to medicines. A more balanced consideration of established dimensions of access, including acceptability and its associated demand-related factors, may lead to improved global health delivery. This study aimed to explore whether greater consideration of human-centered design – through a focus on product-oriented, demand-related dimensions of access - can lead to improved product innovation, appropriate utilization (i.e. rational use) and perceived efficacy of public health commodities such as Oral Rehydration Salts (ORS). Using ColaLife's innovative diarrhea treatment kit - the Kit Yamoyo - as a basis, we tested whether an increased focus on the acceptability dimension of access and its related components could contribute towards increased odds of appropriate use of ORS.

Having followed the phases of an HCD approach – Hear, Create, Deliver – design decisions focused on improving the acceptability and demand of the diarrhea treatment kit were made. Cross-sectional data collected from household surveys of caregivers in rural Zambia was then used to compare ORS use in diarrhea patients under age 5, who either used Kit Yamoyo or standard one-liter sachets of ORS from rural health centers.

With regard to preparation of ORS in the correct concentration, there was a significant difference between those who used the Kit Yamoyo, developed through a human-centered design approach, as compared to those who used standard one-liter ORS sachets from the health center. Odds of correct ORS preparation were found to be 10.93 times greater ($p<0.001$; 95% CI: 5.74-20.78) in Kit Yamoyo users vs. those that used 1-liter sachets from the health center. Kit users prepared the ORS in the correct concentration 93% (95% CI: 0.89-0.96) of the time, while non-users prepared it in the correct concentration only 60% (95% CI: 0.54-0.66) of the time. Secondary analysis found preparation of ORS in the correct concentration to be

significantly associated with an increase in the odds of perceiving ORS as effective (OR: 1.84, 95% CI: 1.05-3.23, p<0.05), along with having heard a message related to ORS in the previous 3 months (OR: 3.77, 95% CI: 1.72-8.26, p=0.001). Correct preparation was also significantly associated with a decrease in the odds of caregiver's perceiving ORS as effective with each additional year of age (OR: 0.98, 95% CI: 0.96-0.99, p<0.05).

Our findings suggest that a focus on human-centered design and greater consideration of demand-related factors of access, such as acceptability, can lead to improved product innovation and appropriate utilization. This in turn, has the potential to lead to improvements in perceived efficacy of public health commodities. Our findings have implications for how ORS coverage is measured globally, and indicate that coverage levels cited in DHS and other large surveys may actually be much lower when considered from the perspective of whether the ORS was used correctly. This perspective considers something as being "delivered" only once it has been used correctly, and not merely used. Related to this**,** our findings also cast some doubt on the appropriateness of one-liter sachets of ORS for home treatment of diarrhea.

Introduction

Access and Delivery

Previous research has shown that over 60% of childhood mortality could be prevented with full access to existing, often low-cost solutions (Jones et al, 2003). Catalyzed by this revelation, and in order to address existing implementation gaps, the global health community has seen the recent emergence of global health delivery and implementation science as an area of practice and research (Kim et al, 2013; Yamey G, 2012). This emerging discipline draws on many areas of expertise, combines multi-sectoral approaches, and considers the complexities involved in delivering health services in effective, efficient, and equitable ways towards scale.

Central to global health delivery is the concept of access. Common dimensions covered in existing access to medicines frameworks include variations of availability, affordability, geographic accessibility, acceptability, adoption and rational use (Table 3.1) (Bigdeli et al, 2012). Due consideration must be given to both the supply and demand side factors of access under any global health delivery framework. However, while demand-related factors have inherently been a core tenet of commercial business approaches (i.e. based on competition, shifting preferences and user demand), the development community has placed greater emphasis on "perceived need", with predominant focus given to affordability and other supply-related dimensions of access (Jacobs et al, 2011; Yamey G, 2012). When it comes to research around these topics, Kim et al. note, "When assessments of delivery do occur, they are often narrow studies of the cost-effectiveness of a single intervention rather than the complex set of them required to deliver value to patients and their families" (Kim *et al*, 2013).

In many developing nations, delivery through public health services alone has not met the access needs of the poor. This has led to the emergence of markets in response to demands for services and drugs (Bloom *et al.*, 2011). Recent increased attention on the role of health markets (Bennett *et al.*, 2014) has been accompanied by an interest in market-based approaches to improving health delivery, including access to public health commodities (Bloom *et al.,* 2011*)*. With demand being a key driver of markets, this should reinvigorate consideration of demand-related dimensions of access such as acceptability, adoption, and rational use of products of global health significance.

Traditional access to medicines frameworks (WHO/MSH, 2000) identify two determinants of acceptability. The first relates to the actual characteristics of a product or service, while the second focuses on the attitudes and expectations of the user towards a particular product or service. Through a focus on design, these dimensions can be used to facilitate rational use of medicines including rational therapeutic choices and improved use of medicines by the consumer. These factors play an important role in the widespread adoption of the product by end-users and markets more generally. This can be further understood when examining similar principals covered in human-centered design.

Access and Human-Centered Design

IDEO, the leading San Francisco based innovation and design firm, defines human-centered design as "innovation inspired by people". They describe it as a process and set of methods used to create new solutions including products, services, spaces and systems (IDEO, 2011). Design Thinking incorporates end-user insights and rapid prototyping to move beyond assumptions. It is inherently optimistic, collaborative, empathetic, experimental and experiential, addressing the needs of the product's consumer and its enabling infrastructure (Brown & Wyatt, 2010). According to IDEO, key phases in the process include:

- **Hear** – understand needs, desires, aspirations, barriers and constraints of target end-users using qualitative methods; synthesize patterns/themes
- **Create** –recognize existing knowledge; identify opportunities for innovation; brainstorm solutions with the end user's desirability filter in mind; participatory co-design & prototyping; gather feedback

- **Deliver** – identify capabilities required to deliver; create financial model for sustainability; plan pilot and measure impact

While design thinking has traditionally been employed in the business sector, it has clear applications in improving access to global health solutions. Indeed, it is increasingly being employed in the area of social innovation and its principles have been touched on in the literature relating to access at the bottom of the pyramid (BoP) (Prahalad, 2005; Rahman et al., 2014). Prahalad, for example, stressed the need to partner with the poor to "innovate and achieve sustainable win-win scenarios where the poor are actively engaged". This co-creation is an essential element of human-centered design and crucial to understanding and creating user-demand.

Solutions that emerge through human-centered design processes, result from a framework consisting of three lenses: desirability, feasibility, and viability (IDEO, 2011). As with more traditional access frameworks familiar to public health practitioners, these lenses reflect both supply and demand related dimensions, with desirability being central to demand. Desirability refers simply to what people want. Product desirability, more specifically is defined as "the level of desire to consume the product if price is not a consideration" (Garbarino et al, 2003). Based on literature review and case studies, Moultrie and colleagues (Moultrie et al, 2006) identify several "good design" features that influence product desirability. Linking these to the desirability lens of human-centered design and the acceptability dimension of Access to Medicines Frameworks, product desirability can be thought of as a function of:

- *Usability* – ease of use; ability to be maintained/cleaned; clarity of the interface (cognitive usability); physical usability (size, shape).
- *Core benefits* - underlying need for the product; degree of functionality; availability of alternative solutions & perceived value/utility.
- *Aesthetics and sensory appeal* – visual novelty, colors, taste, graphics, material.
- *Symbolic value* - pride of ownership; status; emotional response evoked.
- *Visual clarity* – clear brand identity; clear purpose; consistent with expected values (e.g. caring, responsible, tough, fun, etc.).
- *Product novelty & differentiation* – differentiation of aforementioned factors when compared to similar products that are available; relative advantage

Using ColaLife's innovative diarrhea treatment kit - the Kit Yamoyo - as a basis, we tested whether addressing demand-oriented factors on the supply-side could contribute towards increased rational use of ORS on the demand-side. In this way, this study aimed to explore whether greater consideration of human-centered design – through a focus on product-oriented, demand-related dimensions of access - can lead to improved product innovation, appropriate utilization and perceived efficacy of public health commodities such as Oral Rehydration Salts (ORS).

The remainder of the introduction presents insights from the first phase of the HCD process (i.e. 'Hear'). The Methods section then presents the product-development process from the 'Create" phase (i.e. presented as the Intervention) as well as how impact on rational use and perceived ORS-effectiveness was measured using cross-sectional household surveys (i.e. part of the 'Deliver' phase of HCD). This is followed by the results of the study which focus on the impact of the kit on

rational use and perceived efficacy of ORS. While the decisions relating to the design of the diarrhea treatment kit could also be considered 'results', they are incorporated into the Methods section as part of the Intervention description. This decision was made due in part to the design choices being integral to the 'Create' phase of HCD, and their centrality to the intervention (i.e. the kit), hypothesized to improve rational use and perceived efficacy of ORS. This decision also helped to facilitate greater clarity and flow.

The Need For Improving Access To Diarrhea Treatment

Globally, diarrhea is the second leading infectious cause of childhood mortality (Liu et al, 2015), with approximately 600,000 children under age 5 losing their lives to this largely preventable disease each year (UNICEF, 2013). These deaths occur within the context of the global health community being fully aware of the treatment needed to successfully manage the vast majority of uncomplicated diarrhea cases. Low-osmolarity Oral Rehydration Salts (ORS) and Zinc supplementation for 10-14 days are safe and effective in both home and facility settings when properly prepared and administered (Awasthi S, 2006; Bhandari N et al, 2008*)*. Together, these medicines make up the globally recommended treatment for diarrhoea, which has been in place for more than 10 years (WHO/UNICEF, 2004). ORS has been shown to remedy more than 90% of dehydration from diarrhea (Claeson M et al., 1990). Low-osmolarity ORS more specifically, has been shown to reduce stool output, vomiting, as well as the need for unscheduled intravenous treatment (Hahn S et al., 2002*).* In a review of 205 studies, use of ORS was found to have reduced diarrhea specific mortality by 69% and rates of

treatment failure by 0.2% (Munos MK et al., 2010).

Zinc supplementation as an adjunct therapy, has been shown to decrease the severity and duration of diarrhea, as well as provide subsequent protection from recurrence in the 2-3 months following treatment (Bhutta ZA, et al, 2000; Strand TA, et al., 2002; Chandyo RK et al. 2002; Lazzerini M et al., 2008*).* A review of 13 studies exploring zinc supplementation for diarrhea found that zinc administration was associated with a 46% significant reduction in all cause mortality and a 23% reduction in diarrhea-related hospital admissions (Fischer-Walker CL et al., 2010).

Taken together, ORS and zinc can reduce both morbidity and mortality (Fischer-Walker *et al.,* 2009; Fischer-Walker *et al*., 2010; Munos *et al.,* 2010; Bhandari *et al*., 2008; Fischer-Walker *et al.,* 2011; Baqui *et al*., 2002; Bhutta *et al*., 2013). Estimates have shown that more than 75% of all diarrhea deaths could be averted with full coverage and utilization of zinc and ORS (Jones G et al., 2003). Nonetheless, of those children with acute diarrhea, less than 1% receives zinc and only a third receive ORS globally (Gill 2013; UNICEF, 2012). A 2015 report on Scaling Up Life-Saving Commodities for Women, Children, and Newborns identified low demand and effective use by caregivers as key barriers to improving access to ORS and zinc (Kade *et al*., 2015).

With reference to effective use, while coverage estimates of ORS and zinc are typically derived from reported levels of usage from household surveys (e.g. DHS, MICS, etc.), they do not provide an indication of whether the medicines are actually being prepared or administered correctly (i.e. rational use). Global estimates find that up to 50% of medicines are used incorrectly by patients (WHO, 2004). With reference to ORS more specifically, few published studies have explored whether it

is prepared correctly at the household level. The majority of studies that do exist were conducted in the early 90s and prior.

Barros *et al.* found that 44% of caregivers used less than 800ml of water (i.e. 56% used a sufficient amount) when preparing a sachet that should have been diluted in 1 liter of water (Barros et al., 1991). Only 69% of ORS users in that study used the entire sachet. One study in Nigeria reported that only 62% of users at the household level correctly described how to prepare ORS (Charyeva *et al*., 2015). Another unpublished study from Haiti found that only 40% of ORS users were able to correctly describe how to prepare it (Ward, 1985). A final study from Indonesia demonstrated that 59-69% of caregivers who administered ORS to their children under-2 were able to correctly prepare it (Pulungish, 1992). Caregivers have regularly noted a lack of confidence in administering ORS without health provider consultation, often rooted in uncertainty around preparation and etiology of diarrhea (Blum *et al*., 2011).

Inaccuracies in home-mixing of solutions can lead to electrolyte imbalances like hypernatremia (Fayad *et al*., 1992). According to Nalin *et al*., failure to "ensure correct solution preparation, concentration, and appropriate drinking volumes can lead to electrolyte imbalance, whatever the formulation" (Nalin *et al*., 2004). This incorrect dilution can result in either high or low concentrations of sodium and glucose, which in turn, decrease the effectiveness of oral rehydration therapy for the treatment of dehydration of acute diarrhea (Pulungsih, 1992; Snyder, 1992).

In supporting a recommendation to prioritize use of ORS over home-prepared sugar-salt-solution (SSS), Bhutta *et al.* (2013) note that due to variability in the quality and concentrations of ingredients, and risks of electrolyte

abnormalities in children with severe diarrhoea, the majority of SSS programs have been abandoned. They also cite the fact that many children still have three episodes of diarrhea per year, and that this should stress the need for treatments of proven effectiveness rather than solutions prepared "haphazardly" at home. While the proportion of solutions prepared correctly using ORS is certainly greater than with SSS (Barros, 1991), there is a need to ensure it is consistently prepared correctly, as this too has an influence on demand. While there is evidence that inaccuracies in home-preparation of ORS can be reversed with proper education and health promotion (Fayad *et al*., 1992), a more fail-safe strategy would be to also ensure inclusion of the tools necessary for proper health behavior (i.e. correct dilution). With this in mind, it is also worth understanding the history behind the development of ORS.

History of ORS

ORS, or the discovery of sodium-glucose transport more specifically (the basis for the development of ORS), has been hailed as the most important medical advancement of the 20th century (Lancet, 1978). While seeking out a therapy that could be applied in the field, far away from hospitals and intravenous treatment, scientists conducted much of the early research around ORS within the context of cholera epidemics in the late 1960s and early 70s. However, it was only in the late 1970s that cholera ceased being the primary target for rehydration research. In 1978, the WHO recognized that in non-epidemic seasons, cholera only accounted for less than 5-10% of all acute diarrheas in cholera endemic areas (WHO, 1978). That same year, the Advisory Group for the WHO's Control of Diarrheal Diseases (CDD)

program met in Geneva to study tactics that could be leveraged in the global fight against diarrhea. By the time the CDD program was fully operational in 1980, the standard formula for ORS had already been determined at the 1978 meeting based on the research available at that time (WHO, 1999).

The investigators behind those studies believed that the oral solution should consist of one universal form and quantity to facilitate use by untrained villagers and health care workers under very basic conditions. "They therefore decided on an arbitrary amount, one litre, and hoped for success" (Ruxin, 1994). In terms of the original formulation of ORS, in order to address implementation challenges and develop a single formulation and packaging for global use in both cholera and non-cholera situations, the WHO struck a compromise between the ideal solutions for cholera and non-cholera-related diarrhea (Nalin et al., 2004). Aside from the switch to low-osmolarity ORS in 2004, it is largely this legacy that has shaped guidelines around the non-formulaic aspects (e.g. packaging and quantity) of ORS manufacturing to this day, with one-liter sachets being the norm. Understandably, the focus at that time was on the primacy of the pharmacodynamics behind ORS. The original development of ORS was, therefore, based largely on medical need with less consideration being given to demand-related factors of the consumer. This was made clear when speaking to caregivers of children under-5 in rural Zambia during the 'Hear' phase of the human-centered design approach.

Human-Centered Design in Practice: Key Themes from the HCD "Hear" Phase

Prior to implementation, a key component of the HCD 'hear' phase involved a series of eight focus group discussions with caregivers of children under-5 in rural

Zambia. The specific methodology followed has been captured in more detail elsewhere (Pratt *et al.,* 2012). In short, 82 caregivers from remote rural areas of Katete and Kalomo districts participated in consumer consultations. Focus groups ranged in size from 9 to 12 participants. Qualitative information was gathered to understand challenges faced by caregivers with regard to appropriately treating diarrhea in children under 5. In addition, feedback was solicited on an early prototype of the co-packaged diarrhea treatment kit (DTK) under development for the project.

Key themes emerging from the focus group discussions are discussed further in the methods section and included:

1. Challenges with preparing the standard-issue 1L sachet of ORS from the health centers at the household level;
2. Taste of the ORS obtained from the health centers;
3. Preferences relating to branding and kit components;
4. Willingness to pay (WTP) for a commercially available ORS and zinc product;
5. Long distances to public sector treatment access points; and
6. Regular stock-outs at public sector rural health centers

This paper focuses on the demand-driven themes that helped inform product innovation (1-3), while a parallel paper addresses supply-oriented themes 5 and 6. Cost effectiveness and WTP (4) will be discussed in a future paper. In this way, other key components of the 'deliver' phase are covered elsewhere (Ramchandani, Paper 1). By addressing these supply and demand related themes, our intervention recognized the need for a multi-pronged systems approach; one that acknowledges the complexity of health markets by placing value on optimization of product and

supply chain design decisions simultaneously. This approach – referred to as Design for Supply Chain (DFSC) – builds on the principle that the success of the supply-chain depends on the product and vice-versa. While the literature shows that modeling smaller supply chain sub-problems has been the norm, it also shows that handling these sub-problems separately leads to suboptimal solutions due to a high degree of interdependency (Gokhan *et al.,* 2014). DFSC uses customer, marketing and management requirements for product design, as well as information relating to suppliers and the value-chain as a whole. In industry, this approach has been shown to maximize profit, and also helps reduce the iterations a product design team would go through in order to achieve a successful design, thereby reducing time-to-market (Gokhan *et al*., 2014).

Building on insights from the 'hear" phase of the HCD process, this study sought to explore whether greater consideration of human-centered design and product-oriented, demand-related dimensions of access could lead to improved product innovation, appropriate utilization and perceived efficacy of public health commodities such as Oral Rehydration Salts (ORS).

Methods

Intervention

The Kit Yamoyo® diarrhea treatment kit (Figure 3.1) was developed using a human-centered design approach that closely considered product-oriented, demand-related dimensions of access. In short, it sought to deliver what caregivers want not what we perceive they need. This innovative DTK formed the basis of the intervention in this study. Building on themes from focus group discussions

conducted during the 'hear phase', as well as existing knowledge found in academic literature, the kit and its various design considerations are elaborated upon below. While the resulting outcomes of this study (i.e. rational use and perceived effectiveness) relate directly to the first set of desirability considerations below, we also present the other responsive design features incorporated based the desirability lens of HCD. How the Kit was introduced at the community level and its effect on overall uptake of ORS and zinc is the subject of separate studies (Ramchandani, Paper 1; Ramchandani, Paper 3).

Usability, Core Benefits and the Challenge of the One-Liter ORS Sachet

Two key challenges associated with the standard issue one-liter ORS sachets from health centers (e.g. Government of the Republic of Zambia – GRZ), for home treatment of diarrhea, were highlighted during the focus group discussions. First, caregivers had no standard way of measuring a liter of water. Different household containers were typically used, ranging from beer bottles to teacups to local beverage containers. This creates the risk of preparing a solution that is either too concentrated or too diluted. To address this challenge, we developed the diarrhea treatment kit such that the packaging/container that held the components doubled as a measurement vessel to facilitate proper preparation, mixing and drinking of the ORS.

The second challenge relates to the quantity of ORS prepared with a 1-Liter sachet. A Liter of ORS solution is much more than the average 400ml of ORS a child under-5 typically consumes in a day (Fontaine, 2012; Touchette *et al.*, 1990; Barros *et al.,* 1991). While perhaps appropriate for health facility settings, a 1L sachet is

inappropriate for home use as, on average, more solution will be discarded after 24hrs (~600 mL) than will be consumed by the child (~400 mL). The problem is often amplified in rural settings where accessing water and making it safe for drinking is a challenge. The burden of collecting household water supply, for example, often falls to women and young girls who may walk up to 6km per day in search of water, spending as much as eight hours collecting it (Interagency Task Force on Gender and Water, 2005). This in turn, can prevent them from participating in income-generating activities or attending school. In such circumstances, preparing more ORS solution than is necessary is misaligned with household-level realities. Additionally, once ORS is prepared, WHO guidelines (WHO, 2006) dictate that the solution should be discarded within 24 hours due to increased risk of contamination (Black R et al., 1981; Mathur & Reddy, 1983; Nagarajan *et al.,* 1990; Adhikari *et al*., 1989; Shields *et al.,* 1981). This, in conjunction with previous findings that demonstrate caregivers do not like mixing large quantities of ORS because they do not like to throwaway the unused portions (Sukkary-Stolba, S, 1990), indicate that provision of a 1L sachet for household use may promote incorrect or even risky health behavior.

Typical co-pack formats currently on the market include two 1-liter ORS sachets, with some 500mL sachets being introduced. Health centers usually prescribe one or two 1-liter sachets. Thus, if directions are followed and prepared ORS is consumed within 24 hours, most patients only receive enough sachets for one or two days. Yet, on average, mild episodes last 4.3 days while severe episodes last 8.4 days (Lamberti *et al.,* 2012). Stanton *et al*. found that home-based treatment under such scenarios was inadequate in terms of administered quantity for both

rehydration and maintenance therapy of diarrhoea (Stanton *et al*., 1987). These factors suggest that multiple smaller sachets of ORS would be more appropriate for home use. This is partially reflected in UNICEF's recent addition of 500ml sachets to their supply list (UNICEF, 2015).

With these considerations in mind, the trial version of the Kit Yamoyo was developed to contain eight 4.12g sachets of low-osmolarity ORS that each made up 200ml of solution. Our team worked with a local pharmaceutical company already manufacturing a one-liter sachet approved by the Zambian Medicines Regulatory Authority (ZAMRA), previously the Pharmaceutical Regulatory Authority (PRA), and worked with them to get approval to produce the smaller sachets. The kit packaging was marked with a 200ml measurement line to facilitate proper preparation of each "mini-sachet".

Co-Packaging

Existing evidence suggests that the co-packaging of products, such as ORS and zinc, can influence the perceived value of a product (Meza, 2015). Gill et al. (2013) note that, "co-branding or co-packaging of zinc with ORS could be another way to couple the use of the interventions, and would be relevant to public and private sector outlets." Chopra *et al.* (2013) highlight that production and marketing of flavored ORS or co-packaging of ORS and zinc in collaboration with private sector companies can substantially increase purchase and use of these interventions.

Co-packaging zinc with ORS may also have the added advantage of increasing uptake and perception of ORS effectiveness, which is often considered not to be a treatment per se, but "only for rehydration", thereby limiting its use (Ellis et al,

2007). Multiple studies have found that that provision of zinc can not only increase uptake of ORS, but also decrease unnecessary use of antibiotics (Bhandari et al, 2008; Baqui et al, 2002), which are often thought of as being the strongest medicine for diarrhea (Zwisler et al, 2013). This is also the case, because zinc itself, is often perceived as a medicine. Since caregivers often consider ORS to be insufficient on its own, and often believe an additional treatment should be combined with ORS to cure diarrhea (Ellis et al, 2007), co-packaging should help with acceptability at the community level.

Caregivers in our focus group discussions liked having multiple products in one package (ORS, zinc, soap), perceiving the kit to have greater value as a result. In addition, the ability to see through the packaging and identify the components inside was also highly regarded. Nonetheless, most caregivers did not know what the zinc was, simply identifying them as "pills". Most caregivers recognized the ORS as such, even though they were in smaller sachets. The addition of soap to the DTK seemed to make the kit more attractive, although not all caregivers linked it to hand-washing specifically. Previous analysis has suggested that provision of soap is more effective than education alone (Waddington et al., 2009), and that risk reductions for diarrhea of 48% can be achieved by hand-washing with soap (Cairncross et al, 2010). The soap in the kit was added to add to the attractiveness and perceived value of the kit, and link the messages of prevention and treatment, by promoting hand-washing. The kit packaging included a lid that doubled as a soap dish and separated the soap from the medicinal contents of the kit in line with requirements set forth by the Zambian Medicines Regulatory Authority (ZAMRA). It is for these

reasons that the Kit Yamoyo co-packages low-osmolarity ORS, zinc, and a small bar of hand soap.

Aesthetics and Sensory Appeal, Symbolic Value, and Visual Clarity

Taste

The flavor of the ORS from rural health centers was another factor mentioned during formative work with regard to acceptability of ORS by children. GRZ branded ORS from rural health centers is not flavored. Research from Kenya (Blum *et al*., 2011), Yemen (USAID, 1986), India (Bentley, 1988), and Bangladesh (Baker J *et al.*, 1986) has shown that children tend not to like the taste of unflavored ORS. Although acceptability of a medicine can have multivariate and complex causes, an acceptable taste is critical (Matsui, 2007). While this has been seen as a competitive advantage in the private sector, leading to development of flavored and colored ORS, concerns that flavoring and coloring of ORS may cause over-consumption led the WHO to conduct a safety/efficacy study in Egypt and an acceptability study in the Philippines (Madkour, 1997; Saniel *et al*., 1997 as cited in WHO, 2006). Findings from these studies showed "neither an advantage nor disadvantage for the flavored and colored ORS when compared to the standard ORS with regard to safety, acceptability and correct use" (WHO, 2006). This, along with the aim of making an essential drug available at a lower price in the public health system, led UNICEF and WHO to recommend that governments should use the ORS composition that contains only the four basic ingredients needed to effectively treat dehydration due to diarrhea (WHO, 2006).

In the Saniel *et al.* paper (1997), however, acceptability was not determined through a measure of preference, but by the amounts of ORS consumed at home by children with diarrhea. While reactions to the flavored vs. un-flavored ORS did not differ statistically between groups, it is important to note that the relative acceptability of ORS given to mothers in the context of a consultation at a clinic would likely differ from an over-the-counter market transaction where caregivers were purchasing ORS in the private sector. The authors acknowledge that in such a scenario, flavored ORS could be more attractive than standard ORS, but that this possibility was not tested in their study. The ORS in the Kit Yamoyo is orange flavored and also creates an orange colored solution. Previous analysis has shown that the color of the liquid itself may influence perceived effectiveness and acceptability (Sukkary-Stolba, 1990).

Similarly, masking the metallic taste of zinc has been cited as an important factor in product development (Lazzerini & Ronfani, 2013). Adherence to the entire 10-14 day treatment remains a challenge in programs globally. Other design considerations included the need for tablets to be dispersible and scored if 20mg (for 10mg use in children under 6 months) (Froes, 2001). A study of the acceptability of and adherence to dispersible zinc tablets found that a formulation that took taste, cost and feasibility into consideration was acceptable to children under 5 (Nasrin *et al*., 2005). Over ninety percent of caregivers in that study perceived the tablets were equally or even more acceptable to their children than other medicines. Zinc contained within the Kit Yamoyo comes in a blister pack of 10 pediatric formulated, dispersible, 20mg zinc sulfate tablets. Each tablet is scored down the middle to facilitate use in children less than 6 months of age and had a

sweet coating to mask the naturally metallic taste. During the study, zinc was commercially procured for use in the kits and branded as PedZinc®, but is currently being manufactured locally, along with the 200mL ORS, and branded as NovaZinc®.

Branding

Using brand orientation as a strategy can influence adoption in bottom of the pyramid markets (BoP) of developing and emerging economies (Rahman *et al*., 2013). Prahalad (2005) stressed that the BoP markets are eager to adopt innovations, and are indeed, brand conscious. Others have demonstrated that consumers at the BoP have strong preferences for branded products and purchase them when affordable because they are perceived as providing backing, confidence and quality (D'Andrea, 2006).

During our focus group discussions, caregivers were asked to provide feedback and suggestions on images, colors, and product name. With reference to images, caregivers were presented with options including cartoon lions, a smiling mother holding her child, and various logos including a sad face morphing into a happy face. By far, the most popular image was that of a caring mother holding her smiling child. This literal image was preferred over more abstract logos, yet was reminiscent of the very successful project logo of a seated mother feeding her small child from an ORS campaign in Egypt during the 1980s (figure 2) (Hirschhorn, 1985).

While images are critical to branding strategy (Dichter, 1985), so too is color, which is recognized as an effective means of creating and sustaining brand in customers' minds (Madden *et al*., 2000). Various colors were tested with regard to

the branding of the Kit Yamoyo. Color has been recognized as an important marketing cue with both psychological and sociocultural associations that influence consumer perceptions and consumption behavior (Aslam, 2005; Grossman & Wisenblit, 1999). Orange and red fared well throughout the consultations with potential consumers. This also extended to the orange color of the ORS itself. These factors are likely to be particularly relevant in relation to children under 5, especially when considered from a competitive advantage perspective in the private sector. The final branding for the product included a red and white color scheme with a high quality, realistic photograph of a loving mother looking down at her smiling, healthy child.

The name of a product can greatly influence its acceptability as well. Brand name is a commonly used extrinsic cue to infer perceptions about quality, and can embody a combination of information about a product (Richardson *et al*., 1994). While a brand name needs to be localized within the context of global health, a strong brand name can help control quality perceptions of the product even when its price is discounted (Della Bitta *et al*., 1981). This may be important in scenarios where vouchers or other subsidy mechanisms are used to reach various high-risk segments of the population (e.g. poorest of the poor). Dawar *et al.* (1994) showed that brand name and price discounts can explain up to 85% of the variation in perceived value of a product. ORS related research from Egypt demonstrated that caregivers preferred simple names that conveyed a warm feeling or described the purpose of the solution (Hirschhorn, 1985). The selected brand name in the Egypt campaign was “Mahloul Moalgett et Gaffaff,” meaning “solution for treating

dehydration," but was referred to as "the solution". In Nepal, packaged ORS are called "Jeevan Jal" which translates to "life fluid" (Sukkary-Stolba,1990).

Our work tested a number of names including "Tip Top Tummy", "Top Tum", "Happy and Strong", and "Kit Yamoyo". Caregivers were also asked to consider variations of these names and suggest their own (e.g. "Top Tum", "Box Yamoyo", local translations of "Happy and Strong" and other positive words relating to child health). Kit Yamoyo was by far the most popular brand name option, with the vast majority of caregivers preferring it over the others. Given previous experience, this makes sense. Kit Yamoyo translates to "Kit of Life" or "Life Giving Kit" in the local Nyanja, and plays well into a common local name for ORS, "Manzi Yamoyo" or "Water of Life". "Kit Yamoyo anti-diarrhea kit" was printed in block letters at the center of the leaflet, with the final "o" in Kit Yamoyo resembling a happy face. The recommended retail price (K5.00 = USD $1) was printed on the top right corner of the leaflet. Together, the image, colors and name worked in concert to establish a strong brand identity.

The branding of the product was printed on the back of the Information, Education and Communication (IEC) materials, which helped reduce materials and cost. While the IEC pamphlet had written instructions in two local languages and in English, it focused on the use of simple, clear info-graphics, given that 25% of the adult population in rural Zambia cannot read (DHS, 2007). As opposed to being imprinted on the packaging, the branding and IEC pamphlet was simply an insert that could be easily adapted to meet different needs (i.e. public sector use, localization in another country, etc.). The kit was then heat sealed with all of the contents and branding/IEC pamphlet lying under a tamper proof, micro-porous,

transparent film. The packaging for the kit was originally designed to fit in between the empty spaces in crated bottles of Coca-Cola to facilitate easier transport to the community-level by rural retailers who may be transporting Coca-Cola as well, giving it a unique and differentiating shape (Figure 3.3).

Setting

The study was conducted across four, predominantly agrarian, rural districts in Southern and Eastern Provinces (two districts in each) of Zambia. Two districts served as intervention arms (Kalomo and Katete), and each intervention district had its own matched comparator. Kalomo was matched with Monze in Southern Province, and Katete was matched with Petauke in Eastern Province, giving two sets of intervention and comparator arms. Intervention and comparator districts were matched on a number of relevant criteria including rurality, age distribution of caregivers, education of caregivers, diarrhea burden, and access to treatment (Ramchandani R, Paper 1).

A value-chain for the Kit Yamoyo was established in the two intervention districts (Ramchandani R, Paper 1), making the Kit available through general, community-level retail shops. No kits were made available in the comparator districts. The only alternative source of ORS across rural communities in the intervention and comparator districts was at the facility level through rural health centers. Prior to our intervention, as in most countries around the world, all available ORS in Zambia came in sachets that make up one-liter of solution. This is the standard size of sachets provided at the health center level. In addition, the GRZ

branded ORS is not flavored, not co-packaged (and rarely co-prescribed with zinc), and mothers typically receive two sachets pending on available stock.

Study Design & Statistical Analysis

This study aimed to test whether the application of a new diarrhea treatment kit (Kit Yamoyo), developed using human-centered design, could improve rational use of the product, when compared to standard, one-liter sachets of ORS found in health centers. Whether that was associated with an improvement in perceived efficacy of ORS was also explored. The outcome for the primary analysis was rational use of ORS, defined as preparing the ORS in the correct concentration. This definition is based on one of the core determinants of rational use as defined by the WHO, specifically, improved use of medicines (i.e. ORS) by consumers (Table 3.1). The outcome of the secondary analysis was the perception of effectiveness of ORS. It was hypothesized that a higher proportion of those using the Kit Yamoyo would prepare the solution correctly, and that this would be associated with an increase in perceiving ORS as effective diarrhoea treatment.

For the primary analysis, cross-sectional data gathered through household surveys in each district at endline formed the basis for the analysis. Each district was comprised of 12-15 sites, which provided good geographic coverage of the entire district. Focusing on the sample of children under 5 who had diarrhea in the two weeks preceding our survey and used ORS, we compared Kit Yamoyo users from the intervention districts, with non-users (i.e. 1L health center sachet users), in terms of whether or not ORS was prepared in the correct concentration. In order to

increase power, the sample of non-users was drawn from those using 1-liter ORS sachets in both the intervention and comparator districts.

Intervention district data and comparator district data were pooled after confirming similar outcomes within each arm, respectively. To assess the association between kit use and correct ORS preparation, we used a logistic regression analysis and calculated odds ratio of correct ORS preparation among kit users vs. one-liter sachet users. A robust variance estimate was used to account for within-site correlation of outcomes (Gutierrez R & Drukker D.M., 2007). Confounding diagnostics found that age of the respondent and having heard a message relating to ORS in the previous 3 months were significantly associated with the main predictor of Kit Yamoyo use and were included in the model. We controlled for confounders by calculating adjusted odds ratio using a multivariable logistic regression model.

Given that preparation of ORS in the incorrect concentration can influence its efficacy, we also tested whether preparing ORS in the correct concentration, or other factors related to the introduction of the product (developed through human-centered design), might influence the perception of ORS effectiveness**.** Perceived efficacy of a product is an important determinant of its utilization and adherence (Ilyuk V. *et al.*, 2014; Berg *et al.*, 1993). This certainly seems to be the case with ORS (Blum *et al*., 2011; Zwisler *et al.*, 2013; Grace, 1998; Kumar et al., 1985; Muninjaya et al., 1991). In addition, Rees and colleagues showed that over 40% of patients switch brands and choose alternative medications for any specified condition due to perceptions of poor efficacy (2006). Perceptions around efficacy are therefore significant drivers of patient health and well-being, as well as brand success.

To determine perceived efficacy of ORS, the questionnaire used for the household surveys asked caregivers whether they thought ORS was an effective medicine for the treatment of diarrhea. Confounding diagnostics found that zinc use, exposure to ORS-related messaging in the previous 3 months, and age of the caregiver were significantly associated with the main predictor of preparing ORS in the correct concentration. These covariates were therefore included in the model.

In order to test the association between perceived effectiveness of ORS and its preparation in the correct concentration, we used a logistic regression analysis to calculate the odds ratio of perceived ORS effectiveness among those who prepared the ORS in the correct concentration versus those who did not. In line with the primary analysis, only those caregivers who had a child with diarrhea in the two weeks preceding the survey and used ORS at endline were included in the analysis. A robust variance estimate was used to account for within-site correlation of outcomes, while controlling for potential confounders by calculating adjusted odds ratios using a multivariable logistic regression model. All analyses were conducted using STATA version 13 (StataCorp, 2013).

Sample Size

The main outcome indicator for this study was correct preparation of ORS among children under 5 with diarrhea in the 2 weeks preceding the survey. Diarrhea was defined as experiencing three or more loose or watery stools in the previous 24 hours. An a priori sample size estimation was made prior to baseline in

order to provide 80% power to detect a 30% difference in correct ORS preparation with a two-tailed alpha of 0.05. Assumptions for the calculation were based on previous evidence and included: 60% of caregivers being able to correctly prepare ORS (Charyeva et al, 2015; Bunjamin *et al,* 1990; Ismail and Nazir, 1990; Ward, 1985; Pulungish, 1992), 60% of children with diarrhea receiving ORS (DHS, 2007), and a 25% period prevalence for diarrhea amongst children under 5 (DHS, 2007 and confirmed to be valid during baseline). This resulted in a sample size estimation of 420 children under age 5 in each of the intervention and comparator groups. Given that the sample size used was based on a parent study (Ramchandani R, Paper 1) with more than 600 households with children under 5 per group, the sample size achieved was well within the required estimate for this study.

Study Instruments & Sampling

Household surveys were administered to independent cross-sectional samples of caregivers of children under 5 in two intervention districts, Kalomo and Katete, and their matched comparator districts, Monze and Petauke, respectively. Data collection took place prior to the intervention in August of 2012 (baseline), and after exactly one year of intervention, in August of 2013 (endline). Households in each district were sampled from 12-15 sites/clusters, resulting in good geographic coverage of populated areas across each district. Areas within 10km of the district town ("urban center") were excluded in order to ensure the sample was representative of rural populations in Southern and Eastern province.

No information on the specific locations of households was available during the survey periods. Households were, therefore, selected using a modified random-

walk technique (Turner, 2003) with probability proportional to population size within each site. Cluster/Site population size was determined based on Standard Enumeration Area (SEA) data from the Central Statistics Office (CSO, 2010). After randomly selecting a first household along the perimeter of the site, a sampling interval of 3 was used to determine each successive household. Due to large distances between households in Southern Province, the interval was altered to 1 or 2 (where necessary). An interval of 3 was initially selected to avoid any potential clustering effects and selection bias, but was likely unnecessary in Southern Province given the large distances between most households. If a caregiver of a child under 5 resided in the household but was not available, interviewers attempted to return to the household when logistically feasible.

In each household, the primary caregiver (the vast majority being mothers) of a child under 5 with diarrhea in the two weeks preceding the survey was prioritized for interview. In cases where no child under 5 in the household had diarrhea, the primary caregiver of a child under 5 *without* diarrhea in the previous two weeks was interviewed. They were asked to recall the last time their child had diarrhea (if ever) and about related treatment seeking behavior and knowledge. In instances where multiple caregivers of children under 5 with diarrhea in the previous two weeks existed, the caregiver was selected alphabetically by first name. The same procedure was used in instances where the selected caregiver had multiple children under 5 with diarrhea in the two weeks preceding the survey. Only using a single reference child per household eliminated intra-household correlation. Caregivers had to be at least 15 years of age. A two-week period for identification of diarrhea cases was used in order to minimize recall bias. Only the

sub-sample of caregivers with children under 5 with diarrhea in the two weeks preceding the survey were used for the primary analysis in this study. Both, this sub-sample, and the larger sample of caregivers who had children with or without diarrhea in the two weeks prior to the survey, were used as a basis for the secondary analysis.

Caregivers were asked questions pertaining to how they prepared the ORS solution including the specific ORS product used, its source, the amount of the sachet used during a single preparation, as well as the amount of water used. Correct ORS preparation was defined as preparing the solution in the correct concentration. The reported amount of water used was cross-referenced with reported information on the container used to measure the water, as well as where it was filled to. Interviewers were trained in advance on standard measurements (200ml, 500ml, 1 cup, 1 Liter, etc.), as well as common containers (and their associated measurements) found at the rural household level. In cases where the container used to measure the water was available, interviewers asked for visual verification.

Accurate concentration preparation was determined by cross-tabulating the amount of salts used with the amount of water used. In order to maximize confidence with regard to the accuracy of the prepared ORS solution concentration, analysis only focused on those caregivers who used the entire sachet of ORS. Those who used only part of a sachet were not included in the analysis (n=68) as there was no reliable mechanism for assessing how much ORS powder they had used.

Local enumerators from an external data collection agency, with previous experience conducting household surveys in rural communities, were trained by the

project and administered all surveys (professionally translated and back-translated) in the local language. Surveys were pre-tested in the field by these same enumerators. Surveys typically took between 20 and 60 minutes to complete depending on the responses and whether the Kit Yamoyo had been used. All surveys were carried out on Samsung tablets using Open Data Kit (ODK) software, and were completed within the month of August over the span of three weeks. Consistency checks and skips to avoid entry of erroneous data were automated in the electronic surveys. All data was crosschecked by trained field supervisors on a daily basis and then uploaded to a central server each evening. Uploaded data was then checked by a data specialist from the data collection agency for completeness and consistency, as well as coding of open-ended responses. In case of inconsistency, missing responses, or other questions, the data specialist flagged them for discussion with supervisors and the principal investigator for any necessary follow-up with interviewers.

Ethical Approval

Informed consent was obtained from all respondents prior to survey administration. In cases where the caregiver was under the age of majority, consent was sought from both the head of household and the caregiver themselves. Because this was a low-literacy population, the statement of consent was explained to the caregivers, who then provided signature (if possible) or made their mark using their finger and ink. Both national and district level government health administrations authorized the implementation of the study while community-level approval was obtained through local chiefs. Ethical approval for the study protocol was obtained

from ERES Converge in Zambia, with approval for secondary analysis obtained through Johns Hopkins School of Public Health Institutional Review Board.

Results

A total of 2477 households with at least one child under age 5 were successfully surveyed across all four rural districts at endline. With regard to the primary analysis, household prevalence of diarrhea in children under 5 during the two weeks preceding the survey was 28.4% (n=704). Of those children with diarrhoea, 67.4% (n=475) used ORS across the intervention and comparator districts. We compared those who used the Kit Yamoyo (n=174) vs. those who used standard 1-liter sachets (n=233) with regard to preparing the ORS in the correct concentration. Those users who did not prepare the entire sachet or did not know how much water or sachet-contents were used were excluded from the analysis (n = 68). In order to get more power from our sample of 1-liter sachet users, we included those who used ORS in the comparator areas as well, all of whom used standard 1-liter sachets. Preparing ORS in the correct concentration was deemed to be accurate within 25ml.

We found that only 60% (95% CI: 0.54-0.66) of 1-liter sachet users prepared ORS in the correct concentration when preparing the ORS at home. Of those who used the Kit Yamoyo, with the packaging acting as a measurement vessel, 93% (95% CI: 0.89-0.96) prepared the ORS solution in the correct concentration. Unadjusted odds ratio of correct preparation comparing the Kit Yamoyo users versus one-liter sachet users was 10.7 (95% CI: 5.44-20.97, p <0.001). After adjusting for age and

exposure to ORS messaging during the previous 3 months, odds of correct ORS preparation were found to be 10.93 (95% CI: 5.74-20.78, p<0.001) times greater in Kit Yamoyo users vs. those who used 1-Liter sachets from health centers (Table 3.2).

Secondary analysis compared caregiver perceptions of ORS effectiveness at endline based on those who prepared ORS in the correct concentration (n=104) versus those who did not (n=303) (Table 3.3). Eighty-Seven percent (95%CI: 0.83-0.92) of those who did not prepare the ORS in the correct concentration perceived ORS to be effective. Of those who prepared the ORS in the correct concentration, 93% (95%CI: 0.89-0.96) did. Unadjusted odds ratio of perceived ORS effectiveness comparing those who prepared ORS in the correct concentration versus those who did not was 2.36 (95% CI: 1.24-4.50, p<0.01). We hypothesized other likely factors related to the introduction of the kit that may influence the perceived effectiveness of ORS. These included the improved preparation of ORS, the combination therapy with zinc, and/or exposure to ORS messaging, with the first two factors being directly related to the human-centered design of the kit. After adjusting for these independent variables that we found to be strongly associated with the outcome, odds of perceiving ORS as effective were 1.84 (95% CI: 1.05-3.23, p<0.05) times greater in those who prepared the ORS in the correct concentration vs. those that did not. The age of the caregiver (OR: 0.98, 95% CI: 0.96-0.99, p<0.05) as well as whether the caregiver had heard a message relating to ORS within the previous 3 months (OR: 3.77, 95% CI: 1.72-8.26, p=0.001) were also found to be significant predictors of perceived ORS effectiveness. Of the 100% of Kit Yamoyo users that said they would use ORS the next time their child had diarrhoea (n=173), 99% (95% CI: 97.2-1) of them noted they would use the Kit Yamoyo specifically.

Discussion

A recent analysis of market shaping possibilities for ORS and zinc noted that:

> "*The inefficiencies of the ORS and zinc market have been described as an example of a life-saving treatment stuck in an "uptake trap", wherein a combination of demand- and supply-side inefficiencies work in a mutually reinforcing manner to stifle market growth." (*USAID, 2014; pg. 27)

Our study demonstrates that greater consideration of human-centered design – through a focus on product-oriented, demand-related dimensions of access – can help overcome some of these barriers by facilitating appropriate use and improved user perception of effectiveness. These factors play an important role in increasing adoption (Ramchandani R., Paper 1) and ultimately, improved access. Development of an innovative diarrhea treatment kit - the Kit Yamoyo - was localized to address consumer preferences, private sector activity and other utilization bottlenecks by working with end-users and focusing on product desirability. The Kit Yamoyo design was based on what caregivers said they wanted. This is in contrast to many health products which are designed on the basis of what providers think is needed.

With a focus on optimizing usability, core benefits, aesthetics and sensory appeal, symbolic value, and product novelty and differentiation, we were able to improve product innovation, appropriate utilization (i.e. rational use) and thereby, perceived efficacy of ORS. Leveraging kit packaging to serve as a measurement vessel and reducing the size of ORS sachets to produce 200ml of ORS solution, for example, were direct results of taking a human-centered design approach. It standardized the preparation process and led to improved rational use by enabling ORS to be mixed in the correct concentration. This empowers caregivers by

removing uncertainty, enabling correct health behavior, and giving them more confidence in the ability to effectively treat their children at home. Castano (2014) notes that a process of care that is highly standardized and highly separable from the health facility level provides tremendous potential for business model innovation – one in which a patients expectations and preferences are understood.

Positive health behaviors facilitated by a human-centered designed product were also associated with an improvement in perceived effectiveness of ORS for the treatment of diarrhea. Specifically, the preparation of ORS in the correct concentration, as discussed above, as well as the combination use with zinc (i.e. co-packaging) were found to be positively associated with the outcome. This was in addition to exposure to ORS-related messaging in the previous 3 months, another feature of the overall intervention. As well as delivering the above benefits, the human-centered design approach is fully compatible with the use of existing private sector distribution systems for delivery to remote communities. Private sector distribution systems depend on there being a viable value chain in place. Products that have a high value in the eye of the consumer but are also affordable and profitable for those who sell them along the distribution chain are associated with a robust value chain. A human-centered designed product will have a higher perceived value than a product designed without the participation of customers. This is reflected in the increased utilization of ORS and zinc by children under 5 with diarrhea from less than 1% at baseline to 46% at endline across the intervention districts, while no change was seen in comparator districts (Ramchandani R, Paper 1). In this way, a private sector co-packaged ORS and zinc product based on human-centered design seems to be acceptable at all levels (Ministry, Zambian Medicines

Regulatory Authority, health facilities, NGOs, manufacturer, wholesalers, retailers, caregivers). Appropriate stakeholder development and establishment of multi-sectoral partnerships, along with appropriate social marketing and awareness campaigns were essential complements.

With regard to messaging, a recent study by Wilson and colleagues (Wilson S, 2013) noted that one of the clearest differentiators between nations that have successfully scaled-up ORS versus those that have not was the choice to promote a clear, unambiguous message about the treatment of choice. In this way, linking ORS and zinc-related messaging with specific products, such as Kit Yamoyo, may also improve uptake and awareness of these essential health commodities. In addition, studies in Nigeria and Kenya have indicated that when knowledge and perceived efficacy are in place, caregivers request specific, appropriate treatments (Brieger, W et al, 2004).

This paper also suggests that something cannot be considered delivered, until it is prepared, administered, and used correctly by the end user. The global indicator used to assess our progress in diarrhea treatment – i.e. coverage – is defined as the proportion of children with diarrhea in the 2 weeks preceding a household survey who received ORS (DPWG, 2013). This is based on reported administration of ORS by the caregiver being interviewed. However, our research shows that 40% of caregivers who reported giving ORS to their children prepared it in the incorrect concentration. This has negative consequences with regard to the efficacy of ORS and was likely a conservative estimate given that our analysis only focused on those caregivers who used the entire sachet of ORS. Those who did not prepare the entire sachet are more likely to have prepared a solution of incorrect

concentration (i.e. the proportion of users who prepared the solution incorrectly is likely higher). This has important implications for global health research and policy, given that coverage figures from the DHS, MICS and other routine data collection that are using the current indicator of ORS coverage, likely overestimate the actual "rational use".

This begs the question of whether the global community should be assessing coverage based on the *effective* use of ORS, rather than reported use alone. There is a need for greater confidence in whether the solution is being prepared correctly. However, as with the current coverage indicator, a practical approach under routine data collection would likely require the indicator to be based on "reported" rather than "observed" evidence. Products developed through human-centered design that can help facilitate correct treatment and health behavior may help provide greater confidence in such reported data.

With poor adherence to the 10-14 day zinc regimen being the norm (Nasrin, 2005), similar thinking and further study will be required with reference to effective use of zinc. Future research should focus on how a human-centered design approach might play a role in improving adherence as well as dosage (children under 6 months of age require dosage of half a 20mg tablet, while those older than 6 months require the entire 20mg tablet).

Fischer-Walker and colleagues (2009) have noted that cooperation from private sector manufacturers has helped facilitate uptake of ORS and zinc, particularly in countries that place emphasis on locally produced products. Correspondingly, with a focus on reducing costs, building local capacity, as well as drawing on findings from our research, new kit formats that maintain the key

functions and human-centered design features have been developed for future phases of implementation.

The original kit packaging that was designed to fit in the empty spaces between crated bottles of Coca-Cola was found not to be a key enabler of access. Only a small percentage of retailers used the nesting function to transport kits back to their communities 4-8%). In most cases retailers purchased the kits in bulk and simply used the box they came in to transport them (e.g. on the back of their bicycles). In addition, not all retailers purchased Coca-Cola (~50% carried it always or sometimes - Ramchandani R., Paper 3) at the same time as they were purchasing Kits. This freed the project up from the awkward (yet unique and identifiable), shape of the original Kit, manufactured in the United Kingdom, and allowed for a re-focusing on simpler, lower-cost options. These new formats are manufactured almost 100% locally, and along with incorporation of other lessons from the trial (Appendix 5), have resulted in reduced production costs. With a resulting increase in local orders, including from the public sector, NGOs, and large commercial retailers, this will further translate to price reductions. New formats include a flexi-pack and a screw-top jar (Figure 3.4). Continued research around cost-effectiveness and optimal packaging configuration for effective diarrhea treatment should continue to be a priority.

Limitations

While this study used reported information, it could have been strengthened by actually observing preparation to verify the accuracy of reported solution preparation. However, these studies are logistically more difficult and costly to run

at the household level. A two-week recall period likely helped mitigate against inaccurate reporting. In addition, while there may have been some ambiguity associated with the size of the container used to prepare the ORS solution, it should be noted that interviewers were well trained in describing the containers used when a specific volume was not clear. They also asked for visual confirmation of the containers where available. Training the interviewers in advance so that they had familiarity with a standard cup size, standard liter, as well as common containers found in rural households, helped to ensure a higher degree of confidence in assessments of correct concentration.

While the secondary analysis accounted for important factors hypothesized to influence perceived efficacy, there are likely other factors that would have a significant effect on perception of ORS effectiveness. These may include such factors as caregivers holding a curative theory expectation (i.e. anti-motility, reduced stool output, etc.) versus a re-hydration theory expectation (Coreil & Genece, 1988; Hudelson, 1993); whether ORS was recommended to them by a trusted healthcare provider; whether caregivers paid for the ORS and if so, how much (Baker *et al*., 1985); the acceptability of the product as discussed in this paper (taste, color, branding, etc.); the opinions and perceptions of friends and family; or prior experience with ORS. This last factor is likely to be associated with the age of the caregiver, which in this study was found to be inversely associated with perceived efficacy (i.e. for each additional year, the odds of a caregiver perceiving ORS as effective decreased by 2%). Understanding the reasons behind how this long-term experience might influence perceived efficacy vs. more short-term experience, as

well as expansion of the model to account for other potential factors likely warrants further research.

The study implies that having recently prepared ORS in the correct concentration may affect its perceived efficacy. While the aim of the secondary analysis was simply to explore the association between correct preparation and perceived efficacy, evidence exists to support the notion that a single, positive, recent experience may influence how patients perceive the effectiveness of a pharmaceutical product. In their discussion of efficacy expectations and evidence of consumer biases and heuristics in pharmaceutical marketing, Ilyuk and colleagues (2014) cite the important role of the *availability heuristic*. Closely related is the concept of *attitude accessibility*. The first concept refers to the tendency to judge something (e.g. the probability of perceiving something as efficacious) in terms of how easy it is to recall examples of it (Tversky & Kahneman, 1973). The second concept refers to the strength of the association between a product and an evaluation of it, typically measured by the speed with which people can access the evaluation from memory (Fazio, 1995). In both instances, the more readily information is activated in memory, the greater impact it will have on subsequent judgments (Song & Schwarz, 2009). More recent experiences tend to be recalled more easily (Deese and Kaufman, 1957), and thus it stands to reason that a recent positive experience with the Kit could influence its perceived efficacy. However, as previously noted, memory activation and recall of particular experiences (e.g. treating diarrhoea in children) is likely to differ between older mothers, who perhaps have more experience in treating childhood diarrhoea versus younger mothers.

Finally, by excluding those who did not prepare the entire sachet of ORS from our primary analysis, it is likely that our estimate of incorrect preparation of ORS was conservative. While this approach may underestimate the proportion of 1L sachet-users preparing the solution incorrectly, the decision was made to try and maximize the accuracy with which we determined the concentration of the prepared ORS solution. Presenting a conservative figure with a higher degree of confidence was deemed to be more powerful than the alternative.

Conclusion

From ORS' humble beginnings as a treatment in cholera camps; to a revised formula, and the addition of zinc to the global recommendation; to an increased focus on expanding coverage and delivering impact at the community and population level; our study positions itself in a progressive line of evidence from the efficacy of ORS and zinc at the individual level to their community-level utilization. Situated at the intersection of global health innovation, health markets, multi-sectoral partnerships, human-centered design, and global health delivery, it is one few studies to empirically link human-centered design and improved treatment practices in a global health context. It shows the effectiveness of giving greater consideration to demand-related factors at the base of the pyramid, and how this plays into improved delivery and rational use. We believe that our findings have important implications from both a policy perspective, with reference to how we measure success in combatting diarrhea, as well as a product configuration perspective with regard to ORS and zinc.

Figures for Chapter 3

FIGURE 3:1: ORIGINAL KIT YAMOYO & CONTENTS (COLALIFE, 2012)

FIGURE 3:2: "KIT YAMOYO" (ZAMBIA, 2013) & "MAHLOUL MOALGETT ET GAFFAFF" (EGYPT, 1985)

FIGURE 3:3: KIT YAMOYO DIARRHEA TREATMENT KITS IN CRATE OF COCA-COLA

FIGURE 3:4: NEW FORMATS OF KIT YAMOYO – FLEXI-PACK (LEFT) AND SCREW-TOP (RIGHT)

Tables for Chapter 3

TABLE 3.1:COMMON ACCESS TO MEDICINES FRAMEWORKS AND DIMENSIONS

Access To Medicines Framework	Dimensions	Specific Determinants
WHO-MSH 2000 (Center for Pharmaceutical Management 2003)	Availability	• Medicines' supply—type and quantity • Medicines' demand—type and quantity
	Affordability	• Prices of drug products and services • User's income and ability to pay
	Acceptability	• Characteristics of products and services • User's attitudes, expectations of products and services
	Accessibility	• Medicines' supply location • User location
WHO (2004)	Rational Use	• Rational therapeutic choices • Improved medicines' use by consumers
	Affordable Prices	• Medicines' pricing policies
	Sustainable Financing	• Resource mobilization • Pooling • Reduction of out-of-pocket expenditures
	Reliable health and supply systems	• Medicines procurement and supply • Regulation • Human resources
Frost and Reich (2010)	Availability	• Manufacturing • Forecasting • Procurement • Distribution • Delivery
	Affordability	• Government affordability • Non-governmental agency affordability • End-user affordability
	Adoption	• Global adoption • National adoption • Provider adoption • End-user adoption and appropriate use

Source: Bigdeli et al, 2013; *Notes: dimensions highlighted in green fall within the scope of this article*

TABLE 3.2: SAMPLE CHARACTERISTICS

Characteristic	Kit Users (N=174)	1L Sachet Users (N=233)
Mean Age	27 SD=7.9 n=168	29 SD=9.6 n=233
Proportion of Caregivers with above primary education (%)	5% SD=22.5 n=170	9% SD=28.4 n=233
Proportion who heard message to ORS in previous 3 months (%)	71% SD=46 n=174	42% SD=50 n=233
Proportion who Prepared ORS in Correct Concentration (%)	93% SD= 26.4 n=173	60% SD=49.1 n=233

*Sample is based on those ORS users who prepared the entire contents of either the Kit or the standard 1L sachets

TABLE 3.3: ODDS OF CORRECT ORS SOLUTION PREPARATION - ENDLINE, RURAL ZAMBIA, 2013*, A

	Unadjusted, Simple Logistic models		Multivariable logistic regression model	
Characteristic	**Odds Ratio (95% CI)**	**p-value**	**Odds Ratio (95% CI)**	**p-value**
Kit Yamoyo vs. 1L ORS sachet from RHC	10.7 (5.44-20.97)	**<0.001**	10.93 (5.74-20.78)	**<0.001**
Age of Caregiver (for every additional year)	0.98 (0.96-0.99)	**0.007**	0.98 (0.97-1.00)	0.089
Heard message relating to ORS in previous 3 months vs. not	1.48 (1.07-2.06)	**0.019**	0.84 (0.54-1.32)	0.456

*Based on those who prepared the entire contents of the sachet
[A]djusted for within site correlation using robust variance estimate

TABLE 3.4: PERCEPTION OF ORS AS AN EFFECTIVE TREATMENT FOR DIARRHEA - ENDLINE, 2013*, A

	Unadjusted, Simple Logistic models		Adjusted Multivariable logistic regression model	
Characteristic	Odds Ratio (95% CI)	p-value	Odds Ratio (95% CI)	p-value
Prepared ORS in Correct Concentration vs. Incorrect Concentration	2.36 (1.24-4.50)	**0.009**	1.84 (1.05-3.23)	**0.033**
Zinc Use vs. No Zinc Use	2.62 (1.13-6.06)	**0.024**	1.31 (0.57-2.99)	0.521
Heard message relating to ORS in previous 3 months vs. not	3.74 (1.93-7.25)	**<0.001**	3.77 (1.72-8.26)	**0.001**
Age of Caregiver (for every additional year)	0.97 (0.95-0.99)	**0.003**	0.98 (0.96-0.99)	**0.039**

*Based on those who prepared the entire contents of the sachet
Adjusted for within site correlation using robust variance estimate

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Chapter 4 - Serving the Underserved: A Description of Rural, Commercial General Stores as Community-Level Providers of Public Health Commodities in Zambia

Abstract

With growing interest in the potential of market-based solutions to expand coverage of public health goods and services in low- and middle-income countries, there has been a particular interest in the role of private sector retailers. In some countries, commercial retailers commonly selling fast-moving consumer goods (FMCGs) like soap, snacks and beverages may be a particularly effective channel for improving access to certain public health products (PHPs) at the community level. These retailers operate general shops that are often ubiquitous in rural communities, yet little research has gathered information on their characteristics and operations – an essential first step in assessing their potential as informal "providers". With calls to improve our understanding of the various types of providers of health commodities across contexts and settings, this exploratory study aimed to describe some of the features of this retailer type, in rural Zambia, that may have implications for improving access to PHPs.

A cross-sectional retailer survey was carried out across four rural districts of Zambia – two in Southern Province, and two in Eastern Province. General store retailers (n=180) were administered a structured questionnaire that gathered information on infrastructure, staffing, ownership and operations, purchasing patterns, product preferences, and level of engagement with an intervention to expand coverage of a newly introduced diarrhea treatment kit.

Findings provide deeper insight into the operations and characteristics of rural, community-level, commercial retailers. For example, general retailers were open an average of 12 hours, longer than most rural health facilities. Retailers typically purchased goods multiple times per month, from multiple wholesalers, providing increased opportunity for (re)supply of PHPs. The leading motivating factors indicated by retailers for carrying a public health product were helping

children and their community, as well as profit. Average gross margins on other common FMCGs carried by general retailers was 29%, likely applicable to the introduction of PHPs through this channel. Eight-seven percent of retailers noted that they had previously been asked for advice on diarrhea treatment. Following the introduction of a new diarrhea treatment kit, 76% of retailers were found to have it in stock on the day of visit, a stock rate that improves upon rural health facilities.

In rural Zambia there exists a largely untapped potential to leverage general retailers to expand access to important PHPs. Already transporting a variety of FMCGs from central-district to community-level, these retailers may, with the right balance of incentives, serve as effective points of access for basic PHPs such as ORS and zinc.

Keywords supply-chain, retailers, access, private-sector, health-markets, commodities, diarrhea

Introduction

Despite significant progress in addressing childhood mortality, 5.9M children under the age of 5 still die each year (WHO, 2015). The majority of these deaths, and associated morbidity, can be prevented with effective and affordable interventions that prevent or treat the most common causes of illness (PMNCH, 2011; Kade, 2015). Diarrhea for example is the second leading infectious cause of childhood mortality (Liu *et al.,* 2015) and the majority of cases can be effectively managed with oral rehydration salts and zinc (Fischer-Walker *et al*., 2009). Its effective treatment is a priority for integrated community case management of childhood illnesses (ICCM), and a national priority for Ministries of Health when it comes to decreasing childhood morbidity and mortality. Nonetheless, in most low- and middle-income settings, interventions are still not reaching the children that need them. Of those children with acute diarrhea, less than 1% receives

zinc and only a third receives ORS globally (Gill *et al.,* 2013). Thus, there is widespread consensus that improving access and coverage of effective interventions should be a key focus of health policies and associated programs (PMNCH, 2014).

Given that a large proportion of access to health products and services takes place in the private sector in low- and middle-income countries (LMICs) (Hanson & Berman, 1998; Waters *et al.*, 2003), there has been a growing interest in the role of private providers and health-related markets in meeting this objective (Bennett *et al.*, 1997; Bennett *et al.*, 2014). The spread of these markets are perceived by some to respond to weaknesses within the public sector, including under-funding, low motivation and number of healthcare workers, rundown infrastructure, poor governance and inefficient supply chain (Coovadia H. *et al*, 2009; Macfarlane S. *et al*, 2000). It has been argued that private providers can sometimes deliver services that are more accessible, affordable and responsive to the needs and preferences of patients (Smith *et al.,* 2001).

The retail sector accounts for a large proportion of private sector provision in LMICs, particularly for health products (Goodman *et al*., 2009). This is due in large part to retailers often being more geographically accessible, being open for longer hours, providing quicker service, having more reliable drug stock and being perceived as relatively courteous and approachable (Williams and Jones, 2004). Medicine retailers vary in type and include pharmacies and drug shops, patent medicine vendors, market vendors, itinerant hawkers, and general stores (Goodman, 2004). These retailer types range from formal registered pharmacies, to informal private providers (IPPs), to general retailers that may only sell a small number of medicines alongside other goods (Wafula & Goodman, 2010). IPPs have been referred to variously as patent medicine vendors (PMVs), as well as chemical, drug and medicine sellers (Brieger *et al.*, 2004). They can

be found operating out of drug shops, general stores, kiosks, and markets stalls, and also operate as itinerant hawkers (Goodman *et al*., 2007). Shah and colleagues (2010) define IPPs as:

> *Those who provide allopathic medical treatment or services to the public, but have not received formal training in allopathic medicine. These providers operate in a market for health services, and provide alternative sources of health care to the government's public health providers or to non-state providers who have formal qualifications, such as in the for-profit or NGO sectors.*

Goodman notes that very few studies tend to categorize retailers by type of shop (Goodman, 2004). In addition, omission of retailers' main product orientation (i.e. what they specifically focus on selling) also makes distinctions difficult. While IPPs generally refer to those retailers "unqualified" to provide health care services, they predominantly focus on the sale of medicines (although in practice, even medicine sellers often sell other commodities simultaneously) (Brieger *et al.*, 2004; Cross & MacGregor, 2010). The literature often groups these informal retail providers together with more general retailers who operate at the fringe of the medical marketplace. Perhaps the most informal type of 'provider', these general, commercial retailers typically have no formal training in health and generally focus on selling a variety of fast-moving consumer goods (FMCGs) alongside, perhaps, a few medicines (e.g. antipyretics). FMCGs usually refer to non-durable products such as beverages (e.g. colas and juices), toiletries (e.g. soap and toothpaste), and grocery items (e.g. sugar and salt), and may include items such as talk time. As with IPPs, these general retailers also operate out of outlets including grocery stores, general stores, kantemba, and kiosks.

These retailers generally fall within the informal or microenterprise category. Although the terms "informal" and "microenterprise" vary from country to country, in Zambia, they are defined as:

- Informal - total investments (excluding land and buildings) under 50M Zambian Kwacha, less than 10 employees and not being registered with the Registrar of Companies; and

- Microenterprise - total investments under 80M Zambian Kwacha, annual turnover not exceeding 150M Zambian Kwacha, and being registered with the Registrar of Companies (note: USD $1 = ~ 5000 ZMK[iii]).

Most informal and microenterprises in Zambia have less than 5 employees (GRZ, 2008). After agriculture, retailer-and-wholesaler trade account for the second largest sector in which informal and microenterprises operate (Conway, 2010).

In sub-Saharan Africa, the number of formal pharmacies is very limited (Goodman, 2007), particularly in rural areas. IPPs tend to be more common in both rural and urban areas of East and West Africa [e.g. Tanzania (Goodman *et al*, 2004), Uganda (Awor, 2012), Ghana (Ansah, 2015), Nigeria (Oshiname & Brieger, 1992), Cameroon (van der Geest, 1987)]. However, in some countries such as Zambia, Malawi and Mozambique, neither of these retailer types is common, particularly in rural areas. As in many developing countries, access to medicines in Zambia's private sector is largely confined to pharmacies and drug shops in urban settings (Goodman, 2004; McCabe *et al.,* 2011; Yadav *et al*, 2012; Cohen *et al*., 2010; Wafula *et al*., 2012). The fact that there are less than 100 pharmacists (i.e. Bachelor of Pharmacy) in Zambia and only 59 pharmacies (40 of which are in Lusaka) contributes to this confinement. Similarly, the lack of pharmacy technicians (i.e. diploma in pharmacy) in the country also keeps the number of drug shops low (Dalberg, 2008).

All private pharmaceutical importers, wholesalers, and retail pharmacies in the country are required to employ a pharmacist registered with the Medical Council of

[iii] ZMK is now the outdated Zambian currency. New Zambian currency is ZMW (USD $1 = 5 ZMW). Conversion rate as of August 2013 (end of trial).

Zambia (Palafox *et al*., 2012). Licenses for the manufacturing, importation, wholesale and pharmacy retail of medicines are issued by the Zambian Medicines Regulatory Authority (ZAMRA, previously the Pharmaceutical Regulatory Authority or PRA). The functions of the Authority as stipulated by the Medicines and Allied substances Act of 2013 include the regulation and control of the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances. It covers the registration of products, pharmacies, health shops and agro-veterinary shops. It is also responsible for post-marketing surveillance.

Drug shops, registered with local governments rather than licensed by ZAMRA, are not required to employ a pharmacist. While they are only supposed to dispense over-the-counter medicines, in practice, some also dispense prescription only medicines. These retail outlets are mostly limited to urban centers. Medicine prices and mark-ups within these private sector outlets are not regulated and are established by the market. General stores that focus mainly on the sale of FMCGs are another source of a limited number of over-the-counter medicines. Very little is known about these outlet types, and the literature on their characteristics and behaviors in Zambia is extremely limited. These outlets fall within the aforementioned informal microenterprise category.

In rural Zambia, access to health care products and services is thus largely limited to public sector facilities. Here, a number of physical barriers to access are cited including: “insufficient infrastructure; inaccessibility due to geographic factors; sparsely distributed populations in rural areas; inadequate resources for outreach (fuel, vehicles, etc.); and poor scheduling of services leading to missed opportunities” (Ministry of Health, 2010). One rural Zambian study found that distance was a significant predictor of attendance for diarrhea treatment specifically (Chatt & Robert, 2010). In addition to

geographic access barriers, public sector facilities face regular stock outs of essential medicines like ORS and zinc. Thus, despite basic medicines being made available at no cost to patients as of 2006 (Masiye *et al*., 2010), essential and life-saving drugs were still widely unavailable in health facilities (Picazo and Zhao, 2008).

In these places, the commercial private sector, and micro-enterprises like general retailers who focus on the sale of FMCGs more specifically, may provide a suitable outlet for expanding access and coverage to public health products (PHPs) at the community level. For the purposes of this analysis, PHPs are defined as products used for promoting health or for the prevention, management or treatment of diseases of public health significance. These can typically be provided at the general retail level without the delivery of an associated service (Conteh & Hanson, 2003). Examples of PHPs include, but are not limited to: mosquito nets, water purification tablets, condoms, micronutrient supplements (e.g. Sprinkles, Vitamin A, etc.), soap, and certain over-the-counter (OTC) medicines like ORS and zinc for diarrhoea.[iv]

Operating out of fixed premises, these shops are ubiquitous in rural areas around the world and run on a for-profit basis. This has the added benefit of contributing towards local livelihoods. However, when it comes to understanding the potential of these retailers to provide PHPs, very little is known about them, particularly from a global health perspective. Few studies have attempted to address this gap and there is a need to expand geographic coverage of existing studies in order to cover a wider range of settings, capture potential variations, as well as different types of medicine sellers (Goodman *et al*., 2007).

[iv] Zinc now has over-the-counter status in most countries, but is still "in progress" or not yet secured in others; as of 2013, of the 10 countries with the highest burden of child deaths from diarrhea: India, Nigeria, Pakistan, Kenya, Bangladesh and China have achieved OTC status; DRC and Uganda are "in progress"; and Ethiopia and Niger have not yet secured OTC status. Zinc is OTC in Zambia. (Unger CC, et al. Arch Dis Child 2013;0:1–6.)

Understanding the nature of various private providers is an important first step in the design of appropriate and effective strategies to increase coverage. In this study, we address this issue by exploring the potential suitability of general, commercial retailers for carrying PHPs, such as over-the-counter ORS and zinc, in Zambia. Taking a descriptive lens, this paper explores the infrastructure, staffing, ownership and operations, purchasing patterns and product preferences associated with these retail shops, as well as their level of engagement with an intervention to expand coverage of an innovative diarrhea treatment kit. It thereby attempts to shed light on the potential of these outlets to expand access to appropriate PHPs, particularly in rural areas.

It has been suggested that expanding access to treatment for diarrhea could benefit from private sector, market-based approaches (*Fischer-Walker et al., 2009; Gill et al., 2013*). The World Health Organization (WHO) and UNICEF advocate strategies to improve home-based management of diarrhea (UNICEF/WHO, 2009), with retailer interventions seen as one possible facilitator. ORS and zinc can be taken without much guidance or with simple instructions; there is minimal risk associated with their use (e.g. no threat of resistance); and they are recommended regardless of the causal agent. Timely and appropriate treatment of children under-5 years of age is particularly important in preventing dehydration and curtailing morbidity and mortality. Providing care through such retailers, closer to the household level, may be one way of addressing this.

In order to better understand the provider landscape in Zambia, Appendix 6 outlines the sources of pharmaceuticals at all levels of the health system, including both public and private outlets. The general retailer types that are the subject of this paper are highlighted in green. They included independent general stores, kiosks, and kantemba

commonly found across the "last-mile" in rural Zambia and who focus on the sale of FMCGs (Appendix 6).

Methods

Setting

This exploratory study was conducted in four rural districts of Zambia – Kalomo and Monze in Southern Province, and Katete and Petauke in Eastern Province. The districts are 200-480km from Lusaka with few paved roads outside of the district towns. As in most of rural Zambia, access to health care products and services is predominantly through public sector health facilities. However, only 50% of rural households have a health facility within 5km (Chankova and Sulzbach, 2006).

The four districts were purposively selected as representative of a typical rural setting in Zambia, with high burden of diarrhea in children under-5, limited access and unreliable effective use of ORS and zinc, and presence of community-level general stores spread throughout the districts. Further district selection criteria associated with the larger study are outlined elsewhere (Ramchandani, Paper 1).

Data were collected as part of a larger study focused on determining the effect of emulating commercial, private sector value-chains on uptake of ORS and Zinc (in the form of a newly introduced diarrhea treatment kit – Kit Yamoyo®) for childhood diarrhea (Ramchandani R., Paper 1). Information gathered from this general retailer study was used to inform the market introduction of the Kit.

Retailer Survey

Data were gathered across all four districts using retailer surveys. A structured questionnaire was administered to proprietors (shop owners in most cases) of community-level, commercial, general retail outlets commonly found throughout rural Zambia. Surveys were administered by trained, local enumerators in face-to-face interviews with the retailer. Enumerators were recruited through an external data collection agency. All enumerators had previous survey experience. They were trained by the project over the course of one week and administered all surveys in the local language (professionally translated and back-translated). Surveys typically took between 40 and 60 minutes to complete. Fieldwork was carried out over the span of three weeks. All surveys were carried out on Samsung tablets using Open Data Kit (ODK) software.

The retail outlet survey used a questionnaire with both closed and open-ended questions. Surveys collected data relating to the proprietor of the shops as well as the respondent (usually one and the same); physical aspects of the shop; purchasing, sales and stocking patterns; wholesaler preferences; products carried (including medicines); pricing and profits; and information relating to the customer base. Variables of interest were identified based on project interests, market research frameworks and factors explored in other retailer-focused studies, both within the healthcare and general retail sector (Kumar, 2013; Cheungsuvadee, 2006; Carpenter & Moore, 2006, McCabe, 2011, Wafula *et al.*, 2012). Table 4.1 provides the conceptual framework used to select descriptive factors in assessing the potential of rural retailers to serve as private providers of PHPs.

While the vast majority of the analysis draws on cross-sectional data gathered during the midline of the larger study in March of 2013, information relating to the

experience of retailers with regard to selling Kit Yamoyo was also gathered at endline (2013). Therefore, in order to highlight the level of retailer engagement and motivating factors for becoming a Kit Yamoyo retailer, some results also draw on the endline survey conducted in August of 2013. The latter analysis draws only on data gathered in the two districts that received the intervention as part of the larger study (Kalomo and Katete).

Midline data were used for the majority of analyses, as the dataset was more complete and some of the questions were refined in the midline questionnaire based on lessons from the baseline. Given the variables of interest for this study, there was limited concern with regard to potential bias associated with using midline data rather than baseline data. In the cases of analyses where the larger intervention may have influenced the variables of interest (e.g. diarrhea treatments carried) the analysis was adjusted appropriately and is addressed within the results section. GPS coordinates for the shops were also gathered and used for outlet mapping. This resulted in an open source, interactive Google map that has been published separately and shows the locations and basic information pertaining to selected shops[v].

Sampling

A recognized challenge when trying to construct a sampling frame of retailers within districts is that the number and locations of informal retailers are often not known (Conteh & Hanson, 2003). Formally, once a company is officially registered, the business is supposed to submit a copy of the company certificate to the licensing officer at the local (district-level) council. Discussions with district council officials, however, revealed that records of registered shops were typically incomplete or outdated. This is supported

[v] http://www.colalife.org/2013/05/13/a-virtual-tour-of-the-kit-yamoyo-retailers/

by findings from the Zambia Business Survey (Conway, 2010), which found that only 5% of firms in the informal, micro and small enterprises (MSME) universe reported having municipal licenses, only 3% reported being commercially registered, and only 2% reported having a tax identification number from the Zambia Revenue Authority (GRZ, 2008). Informal and microenterprises typically do not comply with licensing requirements, particularly if they are located in areas designated as disadvantaged (UNCTAD, 1998).

Because of this lack of insight into the population or universe of retailers, we first conducted a pre-study census, or inventory of general retailer shops. In order to identify as many rural general shops as possible within each district, each district-level, centrally located wholesaler that was participating in the larger study was first approached to identify retailers that purchased from them. However, these types of records were typically not kept, and they were able to offer little insight into the numbers or locations of their clientele. Identification of shops was thus done in coordination with key stakeholders including the District Planner from each district who physically accompanied the research team, resulting in a sampling frame of between 55 and 65 retailers per district. Based on discussions with district council officials, the sampling frames for each district were perceived to be relatively close to the actual total population of rural, community-level retailers within them.

Once retailers were located, their coordinates were recorded using GPS and then mapped using GIS software. In many communities, groups of retailers were clustered together in one particular area (i.e. a "shopping center"). Using GIS software, we were able to group retailers into 12-15 clusters/sites per district, with one or more retailers forming the center of each site and providing good geographic coverage of rural areas

within the entire district. These sites helped form the basis for the sampling strategy used as part of the larger related study (Ramchandani, Paper 1, Figure 2.3). Parts of the district close to or within town ("urban center") were not part of the "census" of shops and were excluded so as to maintain focus on rural parts of the districts only. All sites were at least 10km from the district town.

Sample Size

Based on the market needs of the larger intervention, budgetary and project considerations, and the clustering of shops within certain communities, a random sample of 45 shops per district was targeted for interview with retailers from all clusters being represented. In order to verify the adequacy of this sample size for estimating population parameters of interest, we used a post-hoc calculation for estimating the sample size required for a descriptive study based on a proportion (Hulley *et al.,* 2013). Very little data is available on general retailers in Zambia, particularly with regard to access of public health products, thus it was difficult to find appropriate reference indicators to assess expected proportion. Reason for not stocking ORS or zinc was one of our outcomes of interest. Thus, the estimated proportion used as a basis for our calculation was drawn from a 2008 outlet survey conducted by the Clinton Health Access Initiative in Zambia, which found that 44% of general retail outlets cited regulatory issues as being the reason for not stocking antimalarial products (CHAI, 2008). Based on a 95% confidence level and precision of 0.18 (CI width), the desirable sample size for the study was estimated at 120. Our study targeted 180 retailers in total.

Data Management, Quality and Analysis

Consistency checks and skips to avoid entry of erroneous data were automated in the electronic surveys. Where applicable, some responses were verified by observing sales receipts and other records volunteered by providers. All data was crosschecked by trained field supervisors on a daily basis and then uploaded to a central server each evening. Uploaded data was then checked by a data specialist from the data collection agency for completeness and consistency, as well as coding of open-ended responses. In cases of inconsistency, missing responses, or other questions, the data specialist flagged them for discussion with supervisors and the principal investigator for any necessary follow-up with interviewers. All analyses were conducted using STATA version 13 (StataCorp, 2013). Unless there were significant differences between districts on particular variables, presented results are based on pooled data across the four districts (except for variables relating to participation by retailers in the larger intervention, which is limited to data from the intervention districts).

Ethical Approval and Consent

Ethical approval for the study protocol was obtained from ERES Converge in Zambia, with approval for secondary analysis obtained through Johns Hopkins School of Public Health Institutional Review Board. Informed consent was obtained from all respondents prior to survey administration. Shop owners were prompted about the surveys during recruitment and training stages, and advised to inform and authorize their employees to cooperate with project researchers during data collection. Owners were also assured that the study was not connected with the tax or drug regulatory authorities, and that data collected would be confidential. Both national and district level government

health administrations authorized the implementation of the study while community-level approval was obtained through local chiefs.

Results

Rural Health Markets in Zambia

A total of 180 retailers were interviewed in March of 2013 – 41 in Katete, 54 in Petauke, 38 in Kalomo, and 47 in Monze. All of the households sampled across the four districts as part of the larger study (Ramchandani, Paper 1) had some form of general retail store within 5km. It is not unreasonable to suggest that this is representative of rural communities throughout the country. These shops typically operated along or close to the main dirt road running through the center of villages. Smaller villages might only have one shop, while larger villages could have a cluster of up to 10 shops forming a community hub. Aside from rotational markets that pop-up at certain intervals in some larger communities (out of scope for this study), these are generally the only places community members can purchase goods on the open market without having to go to the main district town.

Surveyed shops were asked to define what type of shop they were with reference to what they sold. Shops most commonly identified themselves as grocery stores (94%). The second most common identifier used was clothing store (31%) and the third most common was general store (18%). Very few shops identified themselves as having anything to do with medicines or drugs, with only 1 or 2 identifying as such in each district (3% overall). Retailers were able to identify themselves as more than one type of shop. Other less common descriptors included hardware store (9%), tavern/pub (3%), and agro-shop (1%). Eighty-seven percent of shops were owned and 13% were rented.

Infrastructure

The majority of shops were individual, freestanding buildings (Figure 4.1-4.3). Most (82%) had one room while 14% had two, and only 4% reported having 3 or more. 92% of the shops had floors made of cement while the remainder had exposed earth. The roofs of all but one shop were made of metal sheets.

Almost all retailers stored their entire inventory within the shop itself. Sixty-three percent of them kept the inventory solely on the shelves in the shop where the items were displayed for customers, while 34% noted using the shelves as well as some other area within the shop for storage. Only 6 retailers (3%) noted storing goods in a separate building.

General Store Owners, Staff, and Operations

The majority of retailers (Figure 4.4-4.6) interviewed were the shop owners themselves (68%) or family members of the owner (29%). Only 3% of respondents were unrelated employees. Few shops had more than 3 people who worked in them, with most shops having only one (26%) or two (59%) workers, and a few having three (12%). The businesses were predominantly male owned (83%), with only 17% of owners being female. Overall, 67% of respondents were male and 33% were female. The average age of respondents, including owners, was 34.9 years old, while it was 27.9 years old if owners were excluded. The average age of shop owners alone was 38.4 years old. Ages of the respondents ranged from 14 to 83 with a median age of 33.

Retailers, including both owners and staff, generally had the same levels of education. Among retailers, there was no significant difference between males and females ($p=0.715$) with regard to having higher than primary education. Analysis from a

related study (Ramchandani R., Paper 1) shows that this was not the case within the caregiver population, where there was a significant difference between males and females with regard to education levels, with males being more likely to have higher than primary education compared to females (OR=2.5; $p<0.001$). Nonetheless, when compared to the general population of caregivers, retailers' levels of education were significantly higher even after controlling for gender. 29% of retailers had higher than primary education (above grade 9), while only 7% of caregivers did (OR =3.4; $p<0.001$). As with the general population of caregivers (Ramchandani R, Paper 1), education levels of retailers were correspondingly higher in Southern Province districts than in Eastern Province districts.

Opening and closing times were collected from each shop in order to calculate the mean and median hours of operation. Both the mean and median were the same, with shops being open an average of 12 hours per day. Sixty-one percent of shops were open for at least 12 hours, with the minimum amount of time being 5 hours and the maximum being 17 hours. Most shops opened on the hour at 6am (34%), 7am (28%) or 8 am (20%), and closed on the hour at 8pm (31%), 7pm (20%) or 6pm (19%). The vast majority of shops were open year-round, with only a few (8%) being closed during certain periods of the year. The majority of these seasonally closing shops (87%) were concentrated in Petauke with the most likely months of closure being December or January.

Most shops had been running for relatively short periods of time. Sixty-three percent of shops had been in operation for less than 5 years, with 18% running for less than a year. The average length of times shops had been in operation was 5 years, with only 20% of shops having been in operation for 10 or more years. The longest reported time a shop had been running was 30 years.

Only 38% of retailers reported maintaining any kind of records for the store. Of those that kept records, content included the quantity of goods purchased (66%), wholesaler prices for goods (69%), inventory and stock levels (54%), goods sold (49%), retail/sales price (44%), and to a lesser degree profits (16%), credit (6%), and other types of information (10%).

Purchasing Patterns

Most retailers purchased goods from multiple wholesalers. 19% reported purchasing goods from two wholesalers, 28% from three, 27% from four, 8% from five, and 9% from more than five. 2% of respondents were not involved in the purchasing of goods, so were unfamiliar with the total number of wholesalers frequented. Only 7% of retailers purchased exclusively from one wholesaler.

Almost all general retailers reported purchasing goods from wholesalers within their own district. Depending on proximity, some retailers also purchased goods from other districts. Out of all retailers across the four rural districts, 18% also reported purchasing from Lusaka. Table 4.1 shows the proportion of retailers from each project district that reported purchasing goods from wholesalers by location.

Overall, project retailers travelled a reported mean distance of 46km to get to a wholesaler, and a median distance of 35km (IQR=5-230). The distance to wholesaler varied by district, with means, medians and inter-quartile ranges shown in Table 4.2. Most retailers visited wholesalers in order to purchase goods multiple times per month. 29% of retailers visited twice a month, 13% visited three times a month, 27% went four times a month, and 19% made the trip to purchase goods more than four times a month. Only 12% of retailers reported visiting just once a month.

Modes of transport to purchase goods from wholesalers also varied, with the majority of retailers employing public modes of transport (62%). Table 4.3 shows the various modes employed and the proportion of retailers using that mode as their most common form of travel to the wholesaler and for transporting goods.

As the final link in the rural market value-chain for getting products to the community, we wanted to understand retailer opinion on their choice of product supplier. Retailers were therefore asked why they preferred to use particular wholesalers. The price of goods was the most common reason cited for selecting a particular wholesaler, with 86% of retailers identifying it as a key factor. The selection of goods available, specifically having all the items required by retailers, was the second most common reason cited, with 65% of retailers citing it as a key factor. 44% of retailers also identified friendly staff as an important factor, making this the third most common reason cited for selecting a particular wholesaler. Other reasons cited were less frequent, but included the quality of goods, having a credit facility available, transportation related factors such as available routing and lower fees, the security of the shop, as well as regularly offering discounts and promotions.

Retailers spent an average of 1.16M Kwacha (ZMK5000 = $1USD at time of study) during their last wholesaler purchase. However, after removing the top 10% of retailers (by expenditure), who all purchased goods valued at over ZMK 3M, the mean expenditure reduced to ZMK 713,377, with a median expenditure of ZMK 500,000. Expenditures were confirmed by observing the retailer's receipt where available (23%). Figure 4.8 shows the proportion of retailers within our sample and their expenditures during their most recent wholesaler purchase. The top graph includes the expenditure of

all retailers who knew what they spent, while the bottom graph removes the top 10% of retailers and groups the remaining retailer expenditure into 20 bins.

Expenditure relating to transportation varied by the mode of transportation used. Some of the retailers who used public transport incurred charges for transporting goods (i.e. luggage fee based on volume or weight), while others only had to pay for their individual fare. Overall, most incurred a charge for both (67%), while 25% incurred no expenses relating to transportation. Those using private transportation reported expenditures mainly relating to fuel charges. Overall, 74% of retailers in our sample said they incurred some form of expense related to transportation. The majority of retailers who did not incur costs for transporting goods (n=45) used bicycles (73%).

The average cost of transporting goods for those using public transport was ZMK 37,782, with a median expenditure of ZMK 25,000. The mean expenditure for those using private transport was ZMK 172,916, with a median expenditure of ZMK 90,000. Higher expenditures for those transporting goods in private vehicles were mainly associated with fuel charges (e.g. to Lusaka). The individual round-trip fare for those taking public transport averaged ZMK 35,532, with a median of ZMK 30,000. The most common individual round-trip fares paid by retailers taking public transport were ZMK 20,000 (25%), ZMK 30,000 (25%), and ZMK 40,000 (10%).

Goods & Services

An understanding of the fast-moving consumer goods most commonly purchased and sold by rural retailers can help provide insights and lessons for public health commodities, not least of which are the margins that are made and expected by retailers. Table 4.4 summarizes the top ten most common FMCGs reported by rural general stores

based on our sample. The majority of leading brands were local, and on average, retailers made a gross margin of 29%.

Interestingly, with regard to Coca-Cola, a product perceived to be ubiquitous in rural retail shops, only 49% of retailers claimed to always (28%) or only sometimes (21%) carry Coca-Cola. 51% claimed to never carry Coca-Cola. Although Cola was a top FMCG, Coca-Cola was not mentioned as a common brand.

The most important factors considered by retailers when selecting what goods to purchase included customer demand for specific items and profit margins. 94% of retailers cited the former and 67% the latter. Other factors cited, but to a much smaller degree, included the quality of goods as well as having the available capital for purchasing goods.

In the same way some retailers valued wholesalers that provided credit services, they also recognized the value of providing such services to their customers. 79% of retailers in our sample said they sometimes provide items to their customers on credit.

Medicines

Not counting the diarrhea treatment kit introduced as part of the larger study, 53% of retailers said they purchased some type of medicine during their last wholesale purchase. Table 4.5 provides a summary of the types of reported medicines purchased and the proportion of retailers that purchased them. Aside from basic analgesics appropriate for general sale, other medicines were not a common purchase during the most recent wholesaler visit. While medicines not appropriate for general sale were purchased by a small number of retailers, cases were isolated.

Retailers were also asked whether they were selling products for the treatment of diarrhea more specifically. Again, after controlling for the Kit Yamoyo diarrhea treatment kit, thirty percent of retailers claimed to sell at least one type of diarrhea treatment. Retailers reported selling products for the treatment of diarrhea including Panado (7%), Flagyl (21%), Stomache (7%), Indocid (6%) and magnesium (1%). None of these medicines are recommended for the treatment of acute diarrhea.

Of those retailers who claimed to not carry any treatment for diarrhoea, the top reasons provided for not doing so, based on open-ended questioning, included the perception of not being allowed to sell medicines (24%), not knowing what product to sell (23%), not having enough capital (17%), not feeling comfortable selling medicines (11%), rural health centers already providing treatment (18%), and products not being easily available (9%).

It was clear to retailers, however, that diarrhea was an important health issue for children under 5 within their community. When asked to identify the key health issues for children under 5, based on open-ended questioning, malaria (89%), diarrhea (83%) and coughing (69%) were the top responses provided. Eighty-seven percent of retailers noted that they had previously been asked for advice on diarrhea treatment.

To better understand the sophistication of processes in place at rural retail shops, we explored whether retailers had procedures in place to ensure that the earliest items to expire were sold first. This is particularly important for products such as medicines and other perishables. Only 46% of retailers claimed to have processes in place to monitor expiration dates and ensure that those goods to expire first would also be sold first. 54% of retailers had no such processes in place.

Clientele

Retailers reported having more female customers than male customers. Overall 59% of retailers reported that women frequented their stores more often than men, while 29% reported no difference and 12% reported having more male customers.

With regard to daily patronage, retailers were asked how many customers visited their shop during the previous day. On average, shops reported having 31 customers per day with a median of 20 customers per day. The reported number of visits ranged from 0 to 160 customers per day.

Retailer Participation in Provision of Public Health Product (PHP)

Within the context of the larger related study, retailers within two of the districts (i.e. intervention districts) adopted the Kit Yamoyo diarrhea treatment kit as one of their products, becoming outlets for ORS and zinc. The endline survey gathered information relating to their experience. Some of the relevant findings are presented here.

At endline, a total of 77 retailers were surveyed across the intervention districts (36 in Katete, 41 in Kalomo). All of these retail shops had someone attend the training workshops conducted by the project. In the majority of cases - 76% in Kalomo and 97% in Katete - the owner of the shop attended the training. If not the owner, the person was typically a family member who also worked in the shop. Those attending the training were trained to pass along the information/lessons to other employees within the shop, and provided with materials to facilitate proper messaging. It was envisioned that this training would then cascade down to caregivers and clients of these retailers when they were purchasing Kit Yamoyo.

Retailers were trained on topics that were both general (relating to prevention and treatment of diarrhoea) and product specific. All retailers were provided with training materials (in a mostly pictorial calendar-type format). They were encouraged to keep the materials on hand in their shop so they could relay key health messages to customers, including the benefits of the product and when to go to the clinic. While the OTC product was designed to be self-sufficient and not require any attached service, the impact of training and quality of retailer-customer interaction will be an area of future research.

We sought to identify the key motivating factors for involvement in the sale of the diarrhea treatment kit. 90% of retailers identified helping children and their community as the number one reason for being involved. Profit was the second most common response, with 60% of retailers identifying it as a key motivating force. Retailers were also asked what they liked most about selling the kits, with the same responses leading. 62% of retailers in the intervention districts said helping children and the community, while good profit was noted by 30% of retailers.

The vast majority (86%) of retailers did not dislike anything about selling the kit. Of the few retailers that specified something they disliked (n=11), there was a common theme relating to the system in place for the distribution and redemption of vouchers, which were used by the larger intervention to catalyze demand and facilitate access by the poor. Despite any potential challenges faced by retailers, 100% of retailers in the intervention districts planned to continue selling the kit, even after vouchers had been removed from the system. In addition, when asked if they would be interested in participating in a future pilot where they, as retailers, may act as channel distributors for public sector medicines to community level health centers or CHWs, 94% of them said yes. The 6% that said “no” ranged in age from 58 to 83 and cited being “too old” as their

reason for not being interested. Age was found to be a significant predictor of interest in participation, with older retailers being less likely to want to participate in the potential new access to medicines program (OR = 0.86; P<0.01).

Retailers were encouraged to keep a constant stock of kits by project field staff. On the day of the survey, 76% of retailers in the intervention districts had kits in stock. With reference to stock-out duration within the previous month, 49% of retailers reported never being stocked out, 69% reported never being stocked out for more than a week, 80% reported never being stocked out for more than 2 weeks, and 8% reported being stocked out for the entire month. Overall, the average monthly stock-out duration across all retailers in the interventions districts was 7 days.

Discussion

This descriptive study adds important information to the global knowledge base around rural, commercial, private-sector, general retailers operating in markets at "the base of the pyramid" (Prahlad, 2005). With reference to rural Zambian retailers more specifically, it brings to bear previously undocumented analysis that may help inform market-driven public health programming within and outside of the country. While there are other factors that can be assessed, the selected features focused on during this situational analysis facilitate a deeper understanding of how these retailers operate, and are aligned with previous studies exploring private sector retailers operating within health systems.

In addition to larger related studies (Ramchandani, Paper 1 & 2), this paper indicates that the introduction of a diarrhea treatment kit through general retailers is indeed feasible and can improve access. Longer-term follow-up studies with other

products may be useful. It also provides key insights into the characteristics and operations of these retailers, an essential first step in maximizing their value and effectiveness as potential channels for PHPs. Reasons for prioritizing our understanding of these types of providers and the markets they operate in are essential to effective, efficient, and ethical operations – whether in the global health context, or otherwise.

Key reasons for enhancing our understanding of these retailers in global health include the fact that PHPs are typically directed at important public health issues (Conteh and Hanson, 2003); the potential exists for expanding coverage of PHPs, particularly amongst the poor (Ramchandani R., Paper 1); this retailer-type (general retailers) are typically more ubiquitous than pharmacies or drug shops; private providers are generally an important, if not untapped (as in Zambia) source of PHPs; understanding them is a prerequisite for more effective interventions, better regulation and consumer protection (Bloom and Standing, 2008; Peters & Muraleedharan, 2008; Ball, 2011); and there exists a potential for freeing up capacity and resources within the public sector (e.g. task shifting) (Ichoku *et al*., 2013). In addition, understanding these retailers is essential to building a systematic appreciation of these markets in order to support collaboration between key actors and build institutional arrangements that could incentivize better performance (Bloom *et al*., 2011). Stakeholders with interest in these results may consist of Government (both local and national), development agencies, NGOs, social innovators and corporations with interest in emerging markets.

Almost all shops (94%) identified themselves as grocery stores, in addition to other identifiers. Grocery stores generally sell products that are in the FMCGs category. These types of products attract the repeated and frequent patronage of customers resulting in regular contact between shopkeepers and community members. This, in turn, has the

potential advantage of exposing customers to new products, as well as being able to share information on a regular basis. This can be enhanced in the presence of promotional materials, information from the retailer as well as community-level promotion via promoters and radio (Borapich *et al*., 2010). This is particularly relevant in setting where word of mouth plays a strong role in building brands, far more so than in urban areas (Kapur M *et al*., 2014). Thus, the type of shop may have an indirect influence on awareness, access and use of the commodity.

Due to density or clustering of shops in most villages, it is likely possible to gain penetration/coverage within a particular area even if only one shop carries the product. Given that most shops carry the same types of products, even one shop carrying a particular item within these community hubs may incite competition in the market leading to more intensive distribution. Also, given that these hubs are generally the only places to purchase goods at the community level, and are regularly visited by community members, they would likely serve as good locations for social marketing and health promotion activities.

The majority of retail shops in rural Zambia were relatively basic, one-room, brick-and-mortar buildings with cement or dirt floors and metal sheet roofs. Generally speaking, these outlets were not equipped to carry large products and storage was mostly limited to the floor or shelves within the shop. This has implications for the types of products such retailers can carry, limiting them to smaller, more manageable items. This conclusion is further supported by the fact that the majority of retailers used either public transport or bicycles when acquiring goods from wholesalers, limiting their carrying capacity for transporting goods back to the community-level for sale. It is important to note that the physical space used for storage of goods in such shops is in line with the

type of storage conditions one would find for basic non-prescription, non cold-chain requiring medicines in most rural health centers.

Interventions involving training of retailers need to consider how lessons and skills are passed along to other retailers within the shop. Above average levels of education, having only one or two other retailers per shop, and most retailers being family members are factors that will likely facilitate trained retailers being able to pass along training. Training topics gleaned from this research that would be worth covering include, but are not limited to: record keeping, inventory management (e.g. expiration, safe storage and transport, etc.), and of course product-specific benefits (for retailers and users).

The relatively long work hours of rural general store retailers are well above the national average of 8 hours per day within the formal employment sector (CSO, 2008). They also compare well with the operating hours of rural health centers, which according to our analysis of recent IHME data from Zambia (IHME, 2015) is an average of 10 hours per day, although some remain open longer, at least in theory. Holding other factors constant, these longer hours may be associated with improved access to diarrhea treatment, however this analysis was out of scope for the current study.

While closures during certain months of the year were rare, the most common months of closure being December and January makes sense given that these months align well with the peak of the rainy season (Dec-Feb) or what is sometimes called the "hungry season" in Zambia (Jan-March). This is when factors such as a long dry season and a lack of irrigation infrastructure, which result in only one harvest per year, combine with families that rely on subsistence agriculture and a rural economy that is largely agrarian. Harvest income must cover household needs for the subsequent 10-12 months,

but often runs out in the months leading up to the next harvest. Lower levels of disposable income characterize this period (Fink, 2014). If people are buying less during this period, it follows that retailers would be less inclined, and perhaps in less of a position themselves, to purchase goods from wholesalers for sale at the community level. In addition, travel may become more difficult during the heaviest periods of rainfall as road conditions worsen.

While almost all retailers purchased goods from wholesalers within their own districts, a significant proportion of retailers from all districts also purchased goods from Lusaka. This indicates that it may also be beneficial to establish a market for the product within major urban centers, particularly within the context of any scale-up strategy.
In this way, the product may be cascaded into more rural districts, while interventions can focus efforts more centrally. This could be an effective approach in helping shape the national market by providing an access hub for all districts, thereby contributing to longer-term sustainability by providing an anchor supply.

The fact that retailers purchase from multiple wholesalers also has implications for improving availability of PHPs. Rather than having only one location where medicines can be collected by terminal outlets (as is sometimes the case for rural health centers that have to collect stock from the district warehouse themselves), private sector provision through multiple wholesalers for certain PHPs could facilitate wider availability at the community level.

The frequency of visits made by community-level retailers to wholesalers is also relevant. With 88% of retailers visiting a wholesaler two or more times per month, the opportunity for regular re-stocking of goods, including PHPs, improves upon the public sector delivery schedule. Delivery to rural health centers only takes place once or twice a

month, pending on the storage capacity of the facility, in standardized quantities (Vledder, 2015).

Tapping into multiple retailers within a particular geography, who make the trip from communities to district centers on a regular basis, could substantially increase the opportunity for improving availability. This type of atomized distribution, which are channel arrangements that bring products as proximate to customers as possible – usually through small or individual distributors – has been shown to enhance new product adoption in rural markets (Nakata C. & Weidner K., 2012). This type of parallel private sector channel distribution, could complement the traditional three-tier drug distribution system in Zambia (where the central warehouse supplies district warehouses, who in turn send supplies to the health facilities). Further comparisons to the public sector relating to various aspects of distribution would be useful.

Furthermore, these existing distribution channels could go beyond simply complementing the public sector, and in fact help address weaknesses in public sector provision by providing an alternative supply-chain mechanism. General retailers, already transporting goods in small quantities between district centers and the community/village level could be incentivized to act as agents for storage, collection and transport of public sector drugs/kits. While the larger medical supply needs of health centers will likely require ongoing strengthening of public sector supply-chain logistics, utilizing private-sector micro-distribution networks to deliver medicines/kits – particularly basic, OTC, non-cold chain PHPs – to heath centers, health posts and community health workers may be one way of addressing sub-district/sub-HC supply-chain bottlenecks. Such a model could dovetail well with country primary health and integrated community case management (iCCM) services.

By leveraging these existing networks of retailers, as well as the wholesalers that supply them, interventions can avoid large investments in establishing parallel supply chain systems and community-level outlets which are likely to prove difficult to sustain. Given the potential improvements in effective access and utilization, this could represent an extremely cost-effective use of resources and should be studied further. Indeed, studies that have explored cost effectiveness around the use of private pharmacies specifically, both within and outside of Africa, have found this to be the case (Goodman *et al*., 2007).

Retailers identified a number of factors that contributed toward wholesaler preference. These findings would indicate that helping to establish the lowest possible wholesale price (while simultaneously ensuring wholesalers make an acceptable margin), selecting wholesalers that carry a variety of other products commonly carried by rural general stores [i.e. a one stop shop rather than specialized (e.g. pharmaceutical) wholesalers], and good customer service, should be considered when targeting wholesalers to carry a particular PHP. In Zambia general wholesalers are able to obtain a license from ZAMRA to deal in over the counter (General Sales) items, which are required to be marked as such. Addressing the above factors may help facilitate adoption of PHPs by general retailers.

General retailers carried a limited variety of medicines alongside a wider range of fast-moving consumer goods. Similar types of products were carried across the entire sample of retailers. With almost 60% of retailers already carrying some type of basic medicine, it would not be a huge leap to carry other types of basic over-the-counter PHPs. This concept is bolstered by the fact that advice relating to health concerns is sought from general retailers, with most retailers having been queried for advice on diarrhea treatment.

Primary drivers of deciding what products to stock included demand and profit margins, also supported by previous research (Palafox B, *et al*., 2014). In this way, retailers use local demand to drive supply of commodities according to need. Their stocking patterns might even be a way of predicting seasonal needs and disease patterns, a potential area for further investigation.

With regard to selling diarrhea treatment specifically, it was interesting to note that lack of demand was not a reason cited by retailers for not carrying a diarrhea treatment product. Rather, other factors were noted suggesting that training/sensitization activities should take place to introduce new PHPs in order to help familiarize retailers with the product; build their confidence by equipping them with basic knowledge around the product, its management and the health concerns it addresses; as well as explain aspects relating to affordability, profit incentives, where to purchase the product, and any complementarity to public sector provision. These sensitization activities would help address some of the common concerns expressed by general retailers with regard to supplying medicines.

Despite wholesalers within district towns carrying products from multinationals, local brands featured more prominently among the top selling FMCGs (e.g. Havana Cola vs. Coca-Cola). While there may be a variety of contributing factors (e.g. greater familiarity, lower cost, higher margins, greater demand, etc.), further study should explore whether local PHPs fare better than imported products when this comparison is feasible and this type of competition is present. Across the range of products carried, the average gross margin was 29%. Extrapolating to the introduction of PHPs, one might suggest establishing a price point that allows for similar gross margins as other FMCGs, as these levels are acceptable to general retailers. These retailers also seem to have the

capital required to purchase a variety of goods for which there is demand at the community level. The Kit Yamoyo diarrhea treatment kit was sold to retailers for ZMK 3700 and to consumers for ZMK 5000, allowing for a 35% margin (Ramchandani R., Paper 1).

As previously noted in the literature with reference to medicine sellers (Goodman & Brieger, 2007), our research found that rural, general store retailers are also interested and willing to participate in programs relating to health. This was particularly the case where helping children and their communities was concerned, as well as where there was a profit incentive. These were both highlighted as key motivators for participation in the intervention and selling of the Kit Yamoyo diarrhea treatment kit. While profit is important, ensuring that retailers understand the benefits to their communities, and imparting a sense of civic responsibility, would likely appeal to these retailers during any kind of recruitment/training process. Finding the right balance between these motivating factors would be an important part of any attempt in garnering their interest in solutions that help shape the market for PHPs.

To better understand the effectiveness of providing PHPs, including ORS and zinc, through these types of general retailers, continued research is required. This is particularly the case where integration into the entire value-chain for these commodities is concerned. One priority is to compare the quality of advice/services provided by such retailers to those provided by health workers within public-sector facilities. Future studies should use mystery shoppers to assess the quality of interactions with customers as well as the effect of training on provision of health-related information and advice.

Although some treatments, such as ORS and zinc, can be easily administered at the household level, a greater understanding of the differences between provision through

general retailers and the formal health system will be important. In addition, comparing effective household utilization of PHPs based on provision through the public sector vs. the private sector will be important. Certainly, the degree of complexity of the PHP will determine which strategies are appropriate for what product. Complexity can range from a simple product (ORS and zinc, condoms, mosquito nets, etc.) through to products that may require more complex services (STI diagnosis and treatment), on to essential healthcare packages delivered by qualified health professionals. The nature of the product and associated service (along with prevailing regulations) determine the appropriate provider/channel to deliver that PHP (Smith *et al*., 2001).

New Zambian legislation under the Medicines and Allied Substances Act (GRZ, 2013) permitting the establishment of low-level "health shops", similar to those found in Tanzania (Ndomondo-Sigonda, *et al*., 2003), will introduce a new dynamic in the private health markets used by the poor in Zambia. Research around their reach, ability to legitimize potential expanding roles of general retailers, and effect on access will be necessary.

Finally, and more generally, while attempts have been made to develop a typology for the various types of private sector providers and the healthcare products and/or services they offer (Hanson & Berman, 1998), a standard, up-to-date, global taxonomy seems to be lacking. This includes a lack of consistent or systematic descriptions and definitions of private providers across countries and in the literature (Berman & Rose, 1996). With growing interest in the role of health markets, developing such a standard will be of importance. This research, and attempting to better understand various provider types is an essential contribution to any such taxonomy.

Limitations

Our findings were based on one of the more common methodologies used to study private sector supply of public health commodities (Conteh & Hanson, 2003). While retailer surveys are susceptible to various forms of bias, supplementing our research with data form household surveys (Ramchandani, Paper 1 & 2) allowed us to triangulate key variables, and enhance reliability and validity of our data. Being able to compare results at baseline, midline and endline periods also facilitated this. This was one of the factors that helped give confidence in using midline results to present the situational analysis rather than baseline. Nonetheless, as the findings in this paper are, for the most part, based on the midline retailer survey alone, it is worth discussing some of the potential limitations of the study.

The key challenge with such surveys is that gathered information is largely dependent on reporting by the retailer. Thus, various forms of bias may have threatened reliability and validity, including recall bias and social desirability bias. While attempts were made to verify retailer expenditures during their last wholesaler visit by observing receipts, for example, only 23% of retailers provided them. Biases may also result due to sensitivities around specific topics associated with perceived loss of livelihood. For example, if a retailer is involved in the sale of medicines not approved for over-the-counter provision, they may be less forthcoming with information. Future studies would want to incorporate direct observation of in-stock medicines rather than relying only on reported information. A closely related limitation within this study was that, aside from diarrhoea treatments, data on medicines were only collected in the context of what was purchased during the last wholesaler visit. Data was not gathered on all medicines in stock at the time of visit, which may have provided a more complete picture of what

types of medicines can be found at general retail outlets.

The analysis relating to diarrhea treatments carried by retailers controlled for the introduced diarrhea treatment kit. However, because intervention district retailers were trained on the product, including the benefits of ORS and zinc, it is possible that this may have influenced their purchasing patterns with regard to other diarrhea treatments they may otherwise not have purchased.

Finally, with structured surveys mostly quantitative in nature, there can be a risk of over-simplification leading to a lack of breadth and depth. Thus, in addition to using a mixture of methods to triangulate and verify data (including more qualitative approaches), we also attempted to mitigate these potential threats through substantial informal observation of and interaction with retailers. Many of the reported findings in this paper are also congruent with formal research that took place in parallel (Ramchandani, Paper 1 and 2).

Conclusions

In rural Zambia, there is great promise, and a largely untapped potential, in leveraging commercial, private sector, community-level, general store retailers to expand access to important public health products. Already transporting a variety of FMCGs from central-district to community-level, these retailers may, with the right balance of incentives (profit and social), serve as effective complementary points of access [to rural health centers] for basic products of public health significance, such as ORS and zinc. Tapping these underused, existing distribution channels may be a way to improve delivery of PHPs to the community level.

Figures for Chapter 4

FIGURE 4.1: SHOP EXTERIOR

FIGURE 4.2: SHOP EXTERIOR

FIGURE 4.3: SHOP EXTERIOR

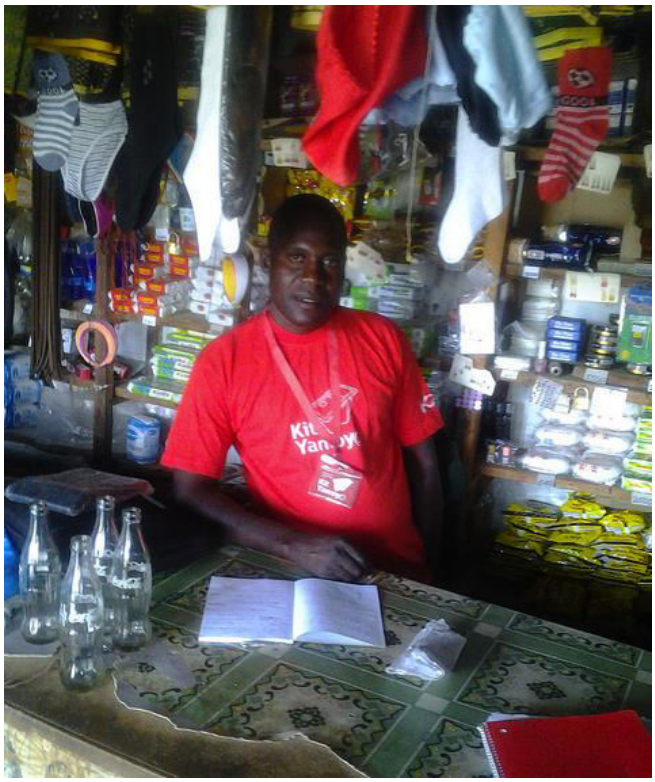
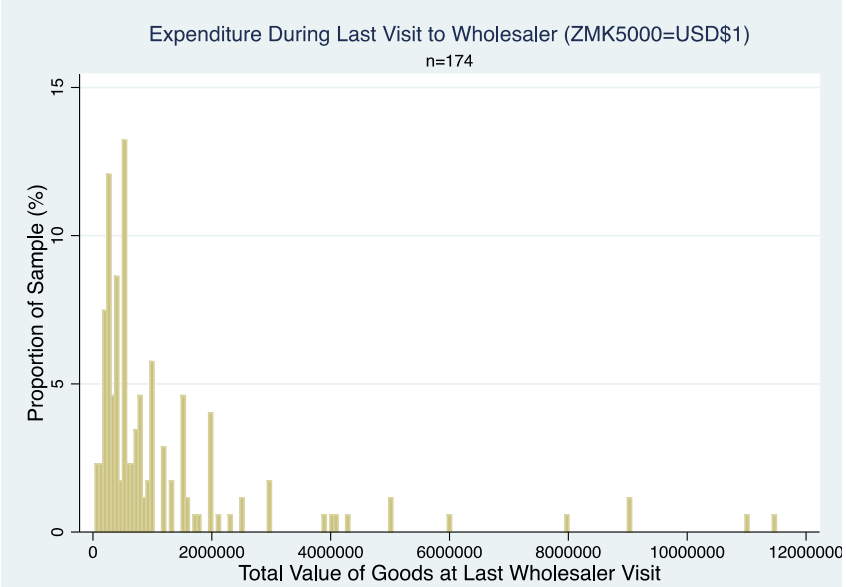


FIGURE 4.4: GENERAL STORE RETAILER

FIGURE 4.5: GENERAL STORE RETAILER

FIGURE 4.6: GENERAL STORE RETAILER

FIGURE 4.7: GENERAL STORE RETAILER



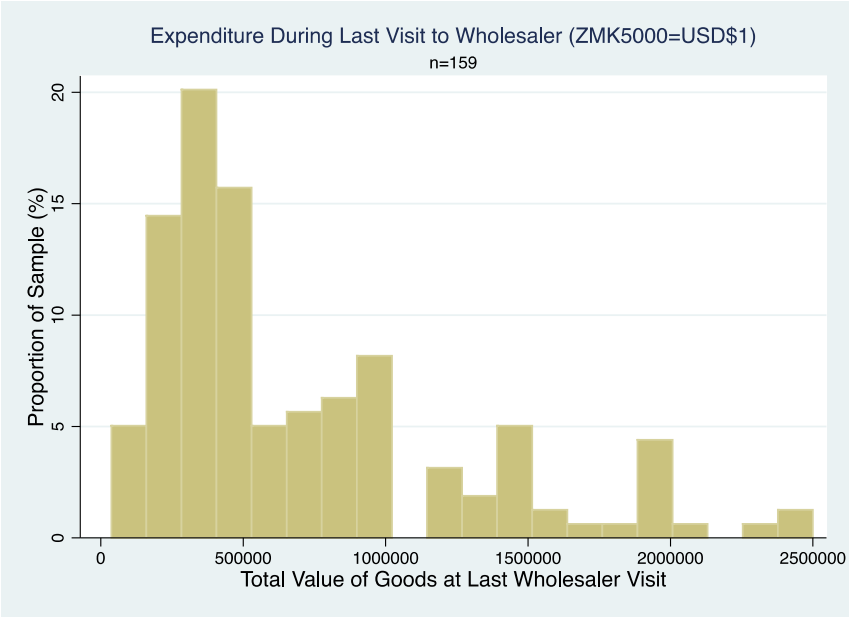


FIGURE 4.8: EXPENDITURE DURING LAST WHOLESALER VISIT

Note: Bottom graph has outliers removed and data are grouped into 20 bins.

Tables for Chapter 4

TABLE 4.1: EXPLORATORY DESCRIPTIVE FACTORS CONSIDERED IN ASSESSING THE POTENTIAL OF RURAL RETAILERS TO SERVE AS PRIVATE PROVIDERS OF PHPs

VARIABLE OF INTEREST	KUMAR, 2013	CHEUNGSUVADEE, 2006	CARPENTER & MOORE, 2006	WAFULA *et al.*, 2012	McCABE *et al.*, 2011
Ownership		X		X	X
Staffing (i.e. demographics)		X		X	X
Physical Aspects of Shop (i.e. infrastructure, set-up, size, facilities, distance, etc.)	X		X	X	
Products & Services (i.e. product mix, prices, stock, margins, credit services, hours, etc.)	X	X	X	X	X
Procurement (i.e. transport, suppliers, preferences, expenditure, etc.)		X		X	X
Customers (demographics, frequency, proximity, etc.)	X	X	X	X	

Note: relevance/application of these factors is explored further in discussion section.

TABLE 4.2: PROPORTION OF RETAILERS PURCHASING GOODS FROM WHOLESALERS BY DISTRICT

	Wholesaler Location								
Project District	Kalomo	Monze	Katete	Petauke	Choma	Chipata	Nakonde	Lilongwe (Malawi)	Lusaka
Kalomo (n=38)	92.11				31.58				31.58
Monze (n=47)		97.87					2.12		14.89
Katete (n=41)			97.56			21.95		2.44	7.32
Petauke (n=54)			1.85	90.74		9.26		1.85	20.37

TABLE 4.3: REPORTED DISTANCE TRAVELED BY RETAILERS TO WHOLESALER (KM)

District	Mean	Median	IQR
Kalomo	62	46	30-86
Monze	47	35	18-50
Katete	38	34	20-50
Petauke	37	25	5-56
Overall	**46**	**35**	**5-230**

TABLE 4.4: MODES OF TRANSPORT USED BY RURAL RETAILERS TO TRANSPORT GOODS FROM DISTRICT LEVEL WHOLESALERS

Mode of Transport Used by Retailers	Proportion of Retailers (%) (n=180)
Public Mode	
Public Van/Bus	29%
Public Truck	21%
Public Car	12%
TOTAL PUBLIC	**62%**
Private Mode	
Bicycle	24%
Private Van/Bus	6%
Private Car	4%
Motorcycle	2%
TOTAL PRIVATE/PERSONAL	**36%**
Other	2%

TABLE 4.5: TOP TEN FAST-MOVING CONSUMER GOODS (FMCGS) FOUND AT RURAL RETAIL SHOPS IN ZAMBIA

Rank	Product[+]	Brands	Most Common Amount/weight of individual unit	Most Common Unit Price (Wholesale)[^]	Retail Price	Profit Margin per Unit	Gross Margin
1	Sugar	brown	1kg	5800	6000-8000	1000-2000	20-25%
2	Refined Edible Vegetable Cooking Oil	**Roical***, Ole, Julie, Mama's, Amanita, Soja, Champion, Ambuya, Amake, Sunflower	750mL	8000	10000-120000	2000-4000	27-33%
3	Laundry Detergent (paste, bar)	**Boom**, Washa, Bullet, Xtra	200g or 400g or 500g	2200 (200g) 3500 (400g) 4500 (500g 2000-2175 & 3600-3900)	3000 5000	700-1000 1400-1500	25-33%
4	Personal Hygiene (soap bar)	**Boom**, Romeo, Chapa, Geza, Yebo	200g and 500g	4500 (500g) 3000-3500 (200g)	5000	1500-2000	30-40%
5	Biscuits	**Chicco**, Petit, Spinners	125-150g	430-1500	500 & 2000	70 & 500	14%-25%
6	Cola/Soda	**Havanna**, King, Thirsty Pop, Mirinda	425mL	1500-2150	3000	1000	33%
7	Talk Time	**MTN, Airtel,** Cellz	NA	variable	1000-2000 (most common)	200	20%
8	Fruit Flavoured Drinks	**Tangy, Best**	350mL	1000-1500	2000-2500	1000	40%-50%
9	Corn Snack	Carnival Jiggies	22g	200-400	500	100-200	25-33%
10	Batteries	Tiger Head	12 batteries	1000-1200	1250-1500	250-300	20%

*Brand names in **bold** signify most common brands mentioned of that particular FMCG
[+] Almost all shops would typically carry each of these products
[^] During the trial, the approximate conversion rate from kwacha to dollar was ZMK 5000 = USD 1

TABLE 4.6: REPORTED MEDICINES PURCHASED BY RURAL GENERAL SHOPS DURING LAST WHOLESALER VISIT

Brand	Medicine Type	Method of Sale	Proportion (%) of Retailers who purchased during last wholesaler visit (n=180)
Panado (Paracetamol)	Analgesic-antipyretic	General Sale	47%
Cafemol	Analgesic-antipyretic	General Sale[3]	38%
Chestcof Syrup	Cough Syrup/Expectorant	General Sale	10%
Indocid (Indomethacin)	Anti-Inflammatory	Pharmacy Medicine[4]	4%
Flagyl[1]	Antibiotic (antimicrobial?)	Prescription Only	3%
Mr. Power[2]	Analgesic-antipyretic	General Sale	3%
Cipium	Sedating Antihistamine	Pharmacy Medicine	2%
Parapain[2] (Paracetamol)	Analgesic-antipyretic	Pharmacy Medicine	1%
Go Coff	Cough Syrup	Pharmacy Medicine	1%
Safeplan	Oral Contraceptive	Prescription Only[5]	0.6%
Fansidar	Antimalarial (SP)	Pharmacy Medicine	0.6%
Stop Cold	Sedating antihistamine – analgesic - antipyretic	Pharmacy Medicine	0.6%
Ibucap	Analgesic-Antipyretic-Anti-inflammatory	Pharmacy Medicine	0.6%
Conjex	Decongestant	General Sale	0.6%
No medicine purchased during last visit	NA	NA	43%

[1]Eastern Province Only
[2]Katete only
[3]General sale medicine (GS) – are medicines which may be sold or supplied to the public without a prescription or the supervision of a registered pharmacist
[4]Pharmacy medicines (P) - are medicines which are not to be sold or supplied to the public except by or under the supervision of the pharmacist or as may be prescribed by an authorized prescriber
[5]Prescription Only Medicines (POM) - are medicines which may be supplied or dispensed only under a prescription issued by an authorized prescriber e.g. all medicines in injectable form

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Chapter 5 : Recommendations Based on Findings

This dissertation examined various aspects of emulating commercial, private-sector value-chains of fast-moving consumer goods, such as Coca-Cola, to improve access to ORS and zinc in rural Zambia. Paper #1 analyzed the overall impact of the systems approach (i.e. addressing both supply and demand related challenges) on uptake of ORS and zinc. Paper #2 explored the application of human-centered design on product development and rational/effective use. Additional analysis aimed to better understand the relationship between rational/effective use and perceived efficacy of ORS. Paper #3 provided a detailed description of rural, commercial, general stores in order to inform the potential of using these outlets as informal, private sector providers of basic public health commodities at the community level. A summary of key findings and their implications for public health are highlighted below as a set of recommendations.

By applying similar principles to the development and introduction of an innovative diarrhea treatment kit, the ColaLife project was able to increase coverage of ORS and zinc combination therapy at the community-level in rural Zambia. Increasing coverage of ORS and zinc combination therapy is a commonly used proxy for reducing diarrhea-related morbidity and mortality in children under-5 (Fischer-Walker & Black, 2010).

A value-chain approach for improving access to over-the-counter public health products, like a diarrhea treatment kit, is the equivalent of applying a health systems approach to public health challenges. It attacks the problem from a variety of perspectives, requires a multi-sectoral approach, and considers issues relating to both supply and demand. Adopting such a lens can significantly improve coverage at the

community level and should be considered when aiming to improve access and coverage of public health commodities. Not all commodities would lend themselves to such an approach, however those that fall into the PHP category, should be considered. While this approach has been taken in certain countries where private sector access is the norm, very little public health literature addresses the concept in detail, and it should be considered in countries such as Zambia, where such access is limited.

Adopting a human-centered design approach in the development of PHPs and other public health interventions allows for greater consideration of demand-related factors of access, such as acceptability, and can lead to improved product innovation, appropriate utilization and perceived efficacy, as well as a strengthened value-chain. Paper #2 revealed the benefits of adopting a human-centered design approach and looking beyond the access domain of price/cost alone.

Evidence that standard 1-liter ORS sachets are often being prepared incorrectly at the household level (i.e. in the wrong concentration) and administered without zinc, has important implications for design and optimal product presentation, as well as appropriateness of setting. While compatible health center utilization (i.e. preparing for multiple patients, HCW preparing, etc.), 1L sachets are not ideal for household level use. In addition, our findings imply that one of the standard global indicators used to measure achievement in the treatment of diarrhea – coverage – may not be an accurate way of measuring progress. Global coverage figures cited for ORS, gathered through large-scale surveys such as DHS and MICS, likely overestimate use when considered from the perspective of whether the ORS is in fact prepared correctly.

Measuring *effective/rational* use of treatments is vital if considering the details of implementation. A medicine cannot be considered delivered until it is accessed and utilized in the correct way. Providing the design features necessary for caregivers to prepare the solution correctly would give the global health community more confidence in such coverage estimates, while simultaneously addressing barriers of access related to acceptability. This research demonstrated that co-packaging of ORS with zinc and soap, smaller sachets of ORS (i.e. 200mL), packaging that doubles as a measurement vessel, and enabling access through community-level general retailers (which presumes ORS and zinc have over-the-counter status) are features of an effective diarrhea product and its value-chain that can help enable greater access, including appropriate use, at the household level.

While there has been a significant amount of research focused on private sector providers, and even informal private providers, very little literature exists on the potential of using general retailers for the supply of PHPs. These retailers are often ubiquitous at the community-level in rural communities around the world. Paper #3 provides a number of relevant insights that would suggest these retailers can be leveraged to improve access and coverage of important public health interventions such as ORS and zinc. This dissertation recommends consideration of these retail outlets as perhaps the most informal of the 'informal private provider' category. Indeed, by narrowing or using too rigid of a definition of competency, that remains within a biomedical paradigm, may limit potential positive contributions of such retailers with the potential to significantly expand coverage of life saving products.

The policy-level interest in such an approach, particularly in the area of product design, is reflected in the broad recognition the project has received from the global health community and beyond. In 2013, PATH, the Government of Norway, the UN Foundation and the MDG Health Alliance featured the original format Kit Yamoyo (i.e. 'The Aidpod') as one of the Top 10 Breakthrough Innovations in Maternal and Child Health (PATH, 2013) at the Every Woman, Every Child event during the UN General Assembly. It was also featured as a Best Buy in Global Health (PSI, 2013) by partners including PATH, PSI, DEVEX and Merck for Mothers in Washington, DC that same year. In addition, part of the research that makes up the current dissertation received a Grand Challenges Rising Stars in Global Health Award. Also in 2013, the Kit was awarded the Product Design of the Year Award by the Design Museum in London, as well as the DuPont Packaging Innovation Award (Diamond level and 'Food Security' awards) in Wilmington. The Kit was also recognized at the Observer Ethical Awards in the 'Products and Services' category. Other accolades have included FastCompany's Innovation by Design Award (Social Good category, 2013), the Financial Times - International Finance Corporation Transformational Business Award in Health (2014), the GSK – Save the Children Healthcare Innovation Award (2015) and the 2015 UK Packaging Awards for the new format flexi-pack Kit (2015). More recently, the global Diarrhea and Pneumonia Working Group featured key lessons learned from our work in Zambia as part of a high-level policy document.

Perhaps one of the most practical policy impacts has been the procurement of co-packaged kits (branded as Government of the Republic of Zambia product) by the Ministry of Health, for distribution through the public sector. This is part of the resulting

national scale-up process (Kit Yamoyo Transition to Scale - KYTS) which is taking place under the global Scaling-Up Nutrition movement, as well as with funding from UK Aid. Zambia is one of the few African nations to have adopted a co-packaged product for distribution through public sector facilities. While this will be done on a trial basis at first in the fourteen most underserved districts, it is hoped that procurement by the MOH will expand to other parts of the country in the long-term.

Future research should continue to explore aspects of establishing and refining value-chains for public health products. This may include testing the quality of interactions with general retailers (i.e. dispensing practices of PHPs, referral practices, knowledge/advice shared with customers, engagement/involvement under new legislation for drug shops) who have received training in provision of a PHP (e.g. through the use of secret shoppers), exploring the range of PHPs that may benefit from expansion by similarly creating complementary points of access in the private sector, distinguishing between those elements of this multi-pronged approach which are necessary and those which are sufficient, as well the implications for access and competition when a product such as the Kit Yamoyo is provided through multiple channels, including the public and private sectors. There is also scope for the public sector to leverage rural, general retailers, who already make the journey from district level centers to rural communities, to deliver products for health facilities across 'the last mile'. Such a model could be an innovative way of leveraging an underused asset to improve upon supply chain challenges seen in the public sector. This also points to the need to explore public-private partnerships at the local, grassroots level, as opposed to being seen solely as ventures

involving large corporations or multi-nationals and global NGOs, which tends to be the standard lens.

References For Chapter 5

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APPENDIX 1: APPLICATION OF GLOBAL HEALTH DELIVERY FRAMEWORK TO COLALIFE MODEL

Delivery Framework Component	Description of Component	Examples of how component was addressed
Use of care delivery value-chains (CDVC)	CDVC lens offers framework for understanding, improvement, and integration of various activities involved in full cycle of care for particular condition Medical condition = set of interrelated patient circumstances involved in full disease cycle across time, including common complications and co-occurring conditions (e.g. pneumonia and diarrhea) Conceives delivery of care (and the creation of patient value) as an overall system, not discrete vertical interventions; stresses the interconnectedness of different components of the care cycle (e.g. prevention; informing and engaging; accessing; intervening; ongoing management; measurement) Activities are tailored to reflect understanding of the disease; taken together, they contribute to patient value and improved health outcomes.	Taking a health systems perspective, and understanding the bottlenecks to effective access and utilization of ORS and zinc, our model took a multi-pronged approach to simultaneously address both supply and demand side factors. By developing an innovative co-packaged product that helps improve proper utilization of the treatments, as well as its end-to-end value chain (bringing treatment closer to home), supplemented by social marketing and health promotion, the intervention aimed to address key issues related to access, awareness and use. More on kit-specific innovations can be found in Paper 2 (e.g. co-packaging ORS, zinc and soap for hand-washing; zinc provides protection against future infection for up to 3 months; etc.) Future efforts could focus on increasing linkages with upstream activities related to nutrition, water, sanitation and hygiene, as well as coordinating approaches for pneumonia and other co-occurring conditions (HIV/AIDS). WASH interventions can increase value by improving the ability to forestall diarrhea incidence. Linking with nutritional programs could help halt the cycle of malnutrition and diarrhea. Nonetheless the overall system was indeed considered resulting in a solution that simultaneously addressed components including prevention (addition od soap to Kit), informing and engaging (via social marketing and health promotion activities), accessing and intervening (via the private sector), ongoing management and measurement. Effective treatment delivery has the potential of replacing inappropriate antibiotic prescription and use, curbing resistance and contributing to overall value of the system. In addition, by bringing treatment closer to the home, caregivers can forgo numerous opportunity costs associated with traveling to a health center to get treatment. Coordination and partnerships with the public sector, from the MOH level (policy, oversight and procurement) to the health facility level compliments private sector access with another value stream. Monitoring and evaluation a core pillar of work within pilot and resulting scale-up initiatives.
Shared delivery infrastructure	Distributes and integrates care delivery for range of conditions across sites of care. While Kim *et al.* limit definition of shared delivery infrastructure to various common components of the health system such as health clinics, district hospitals, referral hospitals, and community-based care, we extend health system concept beyond traditional health facilities to include alternative options such as commercial channels, where appropriate. Shared delivery infrastructure across providers, such as community health workers, health clinics, *or commercial channels* can extend reach and access for patients, and enable care to occur at most	Distributed care delivery to community-level, commercial, private sector shops, but for a single condition. Likely future scope for capturing synergies in care of related pathologies such as pneumonia, malnutrition, etc. (further research required). Leveraged existing networks and infrastructure of kit manufacturer/assembler (Pharmanova), district level wholesalers, Medical Stores Limited (parastatal responsible for transporting medicines for the public sector), and community-level retailers to get product to community-level across the last-mile. Leveraged transport mechanisms including retailers moving product from district centers to community-level via bicycle, motorcycle, truck, etc. Training of retailers coupled with social marketing highlighting issues related to signs of dehydration, when to refer, proper use of the kit and its contents, benefits of contents, enterprise skills.

	effective (including cost-effective) location. Shared delivery infrastructure can enable better leverage of facilities and personnel from different sectors. Task shifting of appropriate product provision and advice have the potential to reduce pressures on already overburdened health facilities and clinical staff. Essential to this is ensuring quality of care, and improved outcomes, and thus value to patients.	
Aligning delivery with external contexts	Within the framework, contextual factors broadly divided into 2 categories: [1)] direct influences on health (e.g. nutrition) and [2)] broader economic and social factors that underlie direct influences (e.g. poverty, education) Direct contextual influences on health can be further categorized: [1)] those affecting the incidence of diseases and injuries; [2)] those affecting ability to access health-care services (e.g., cost, ease of transportation, stigma); and [3)] those affecting the effectiveness of care delivery itself (e.g. adherence to prescribed therapies) Starting point is an understanding of the social circumstances of patients and their families	In Zambia contextual factors included: - MOH supportive of private sector initiatives and local production; - OTC status of Zinc (and ORS) and compatibility with use at the household level; - No private sector access in rural areas with access limited to often distant health centers; - Existing networks of rural retailers already transporting goods across the last mile; - Good level of awareness around ORS amongst caregivers already; - Weak public sector supply chain for medicines with regular stock outs (see Paper 1); - Diarrhea perceived as major health issue by caregivers. Our survey found that 81% of all respondents at endline (n=2477) cited diarrhea as the major health concern amongst children under 5. - 41% of these respondents did not have a toilet (used the bush) - proportion of rural population with access to improved water source: 49% (World Bank Statistics, 2012) - See paper 1 for contextual demand-side factors relating to access
Leveraging the health-care delivery system for economic and social development	Numerous external contextual factors affecting incidence of illness and constraining value of care delivery link directly or indirectly to economic development Harnessing positive linkages with economic development is an essential component of designing value-based systems of global health-care delivery Such systems directly catalyze economic development through 4 primary mechanisms: 1) Healthier population is more productive;	Bringing treatment closer to the home and improving uptake of ORS and zinc by helping to shape the market for an innovative co-packaged kit reduces diarrhea related morbidity and mortality.

	2) Employment; 3) Health systems can drive economic development thru local procurement of goods, services, and equipment 4) Purposeful development of delivery systems in poor communities can be a catalyst for improving infrastructure (e.g. cell phone towers, internet access, electrification, clean water access, and local transportation systems) that will likely have wider economic benefits Health-care organizations that seek out local suppliers and build local capacity can hope for a double impact, as health system procurement can stimulate business and cluster development that goes well beyond the health sector	Working with our private sector pharmaceutical partner, Pharmanova, we have localized production and supply of ORS and zinc in collaboration with the MOH and the Zambian Medicines Authority. All players involved in the value-chain – manufacturer, wholesaler, and retailer - make profit as the product is pulled to the community-level, thereby contributing to livelihoods. Procuring locally keeps money in the local system and has stimulated development of new products within local companies (zinc, small bar of hand soap, packaging, etc.); contributes to GDP

APPENDIX 2: COLALIFE PROJECT LOGIC MODEL

Impact (out of scope)	Contribution towards MDG 4 – reduced childhood mortality – by reducing incidence (and severity) of diarrhea in children 0-59 months in underserved rural communities		
Purpose (will measure up to this level)	Mothers and care-givers of children 0-59 months in underserved rural communities **increase use** of ORS and Zinc in household treatment of diarrhea		
Intermediate Outcome	Increased **Access** by mothers/caregivers of [affordable] Kits (anti-diarrhea kit) in underserved rural communities		-Lessons learnt /results disseminated -Sustainability / exit strategy implemented - multi-sectoral partnership established for last-mile delivery and scale-up/sustainability
Immediate Outcome	**(2)** Improved **availability** of [affordable] Kits (anti-diarrhea kit) in underserved rural communities via profit-driven supply chains	**(1)** Increased **awareness** of Kits and benefits of contents (ORS, Zinc, Soap) among mothers/care-givers	-Relevant data effectively collected and analysed -Where appropriate, new PPPs established for Last Mile supply chain model scale-up -Sustainability/exit strategies/plans agreed/ transferred
Outputs	**1** Kits meet needs at all levels in value chain **2** Novel leverage of the Coca-Cola supply chain meets demand for Kits in under-served communities **3** Retailers and wholesalers trained in benefits of Kits	**4** IEC/Social marketing program for mothers/care-givers on benefits of Kits designed and implemented	-Effective M&E and learning frameworks designed and implemented -Key learnings related to PPP potential in two additional countries identified
Activities	**1.** Design Anti-Diarrhea Kit (ADK) to meet all needs in the value chain: Procure contents: ORS/Zinc, soap Design costing, margins, pricing, subsidy/credit availability, vouchers and tracking Test affordability, desirability and attractiveness of product Design and test packaging (functionality, fit, robustness/damage, tamper-proofing, attractiveness, messaging) **2.** Design and implement novel supply chain leveraging Coca-Cola Last Mile distribution, to meet demand: Implement packing and fulfilment process for the ADK product Distribute Kits to wholesaler level Leverage last mile distribution via Coca-Cola retailers/entrepreneurs **3.** Design/deliver awareness raising, training and follow-up to convey benefits of Kits to retailers and wholesalers 4. Design, test and deliver a social marketing campaign to convey to mothers/care-givers the benefits of Kits: Design, test and produce IEC materials for inclusion in/on Kits Design, test and deliver household-level awareness-raising & training Design, test and deliver community level activity and media channels		5. Design and implement effective M&E framework 6. Develop learning framework to capture additional learnings outside of formal evaluation 7. Formative dissemination of activities and issues via use of social media (open innovation approach) and other venues 8. Design sustainability or exit strategy 9. Explore last mile distribution chains and related Public-Private Partnership (PPPs) opportunities in two other African countries
	Results chain A : Supply Chain ↑	Results Chain B : KAP among Mothers/Care-givers ↑	Knowledge translation ↑

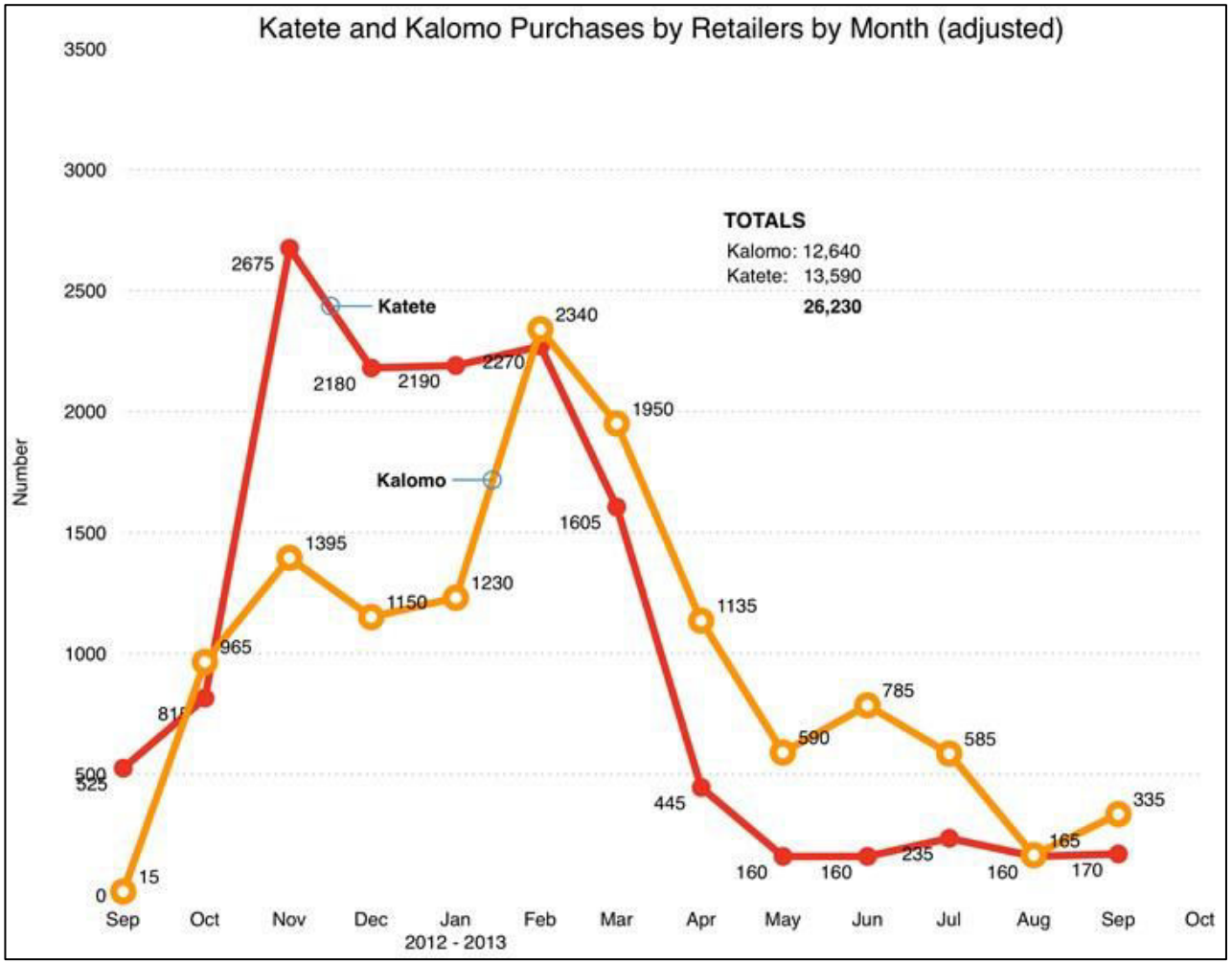
APPENDIX 3: KIT COSTING BREAKDOWN

During the trial there was a top end (manufacturer level) subsidy for the cost of the Kit. The subsidy was intentional and derived from donor funding (i.e. the trial budget). Innovative in design and in content, the Kit was not at a stage, when the trial commenced, where competitive tenders could be sought, economies of scale could be exploited, or local production sourced. During the trial, we were dealing with relatively small production figures, continual innovation, and sourcing from different places (e.g. importing PedZinc from Tanzania, soap from India, packaging from the UK). Since the trial, continual refinement based on trial findings (See Appendix 5), a move towards local production, and economies of scale have led to cost reductions and elimination of the top end subsidy. The tables below show examples of kit costing during the trial and since.

Costs in US Dollars	Aug-12		Jan-16	
	Trial	Notes for Trial Version	Scale-up	Notes for Scale-up (Flexi-pack) Version
Soap	0.23 (13%)	Soap (Novacare - Imported Pharmanova product)	0.13 (25%)	Soap (Novacare - Imported Pharmanova product)
Zinc	0.46 (27%)	PedZinc (blister pack of 10 tablets - imported from Tanzania)	0.12 (32%)	NovaZinc (1 blister pack of 10 tablets - local Pharmanova product)
ORS	0.49 (28%)	NovaLyte (8 x 4.12g/200ml sachets - local Pharmanova product)	0.10 (19%)	NovaLyte (4 x 4.12g/200ml sachets - local Pharmanova product)
Leaflet	0.06 (3%)		0.03 (6%)	
TOTAL Components Cost:	**1.23**		**0.38**	
Packaging	0.28 (16%)	Original Aidpod Format	0.00	Carton cost = $0.45 (K5); 100 kits per carton
Labour/Assembly	0.21 (12%)		0.14 (26%)	Includes assembly overhead; Flexi-Pack Format (flexi-pack=K0.00 (donated), outer polythene bag=K0.04)
TOTAL per Kit	**1.72**		**0.53**	
Price to wholesaler (delivered)	0.65		0.71	Introductory ex-factory price including delivery (34% margin)
Price to Retailer	0.77	Wholesaler makes 19%	0.86	Target wholesale price (21% gross margin)
Price to Customer (RRP)	1.04	Retailer makes 35%	1.16	Target retail price (35% gross margin)
Subsidy:	**1.08**		**0.00**	

Notes: -Percentages are of total kit cost
-Subsidy is based on Total cost/kit minus cost to wholesaler (e.g. USD 1.72-0.65)
-In the trial the wholesale and retail prices were fixed. In the scale-up the market determines the wholesale and retail prices.
-Costings of the scale-up version have been derived during an unprecedented fall in the value of the Zambian Kwacha.Excahnge rate from USD to ZM - 08/12: 1 = 4.8; 01/16: 1 = 11.2
-In Nov-15 Shoprite (national supermarket) entered the market and are buying at the ex-factory price of K8.00 ($0.67) and selling at K8.19 ($0.69). This will undercut wholesalers.
-Shoprite have agreed to allow bulk purchases and will act as 'quasi' wholesalers in the towns/communities where they are located.
-Percentages are of total kit cost

APPENDIX 4: BREAKDOWN OF KIT SALES FROM WHOLESALERS TO COMMUNITY RETAILERS BY MONTH



Kit Sales to 30-Sep-13 were calculated in two ways:

1. By adding up the individual sales to retailers recorded on stock sheets maintained at the wholesaler. These stock sheets were provided by the project and were an add-on to the standard record systems already maintained at the wholesaler level

2. By subtracting the stock levels at the wholesaler on 30-Sep-13 from the total purchases by the wholesaler from the manufacturer

In the case of Katete district, both methods gave the same figure for total sales: 13,590. This was not the case in Kalomo district. The first method gave a total of 11,155 and the second 12,640 – a 13.3% difference. The difference can be attributed to inaccuracies in the recording of individual sales to retailers by wholesalers in Kalomo. At busy times the recording will have been overlooked. The Kalomo wholesaler was equally well run as the wholesaler in Katete but in Kalomo, any one of multiple employees kept the stock sheet recording individual sales to retailers. In contrast, the wholesaler in Katete was run by the owner and the records of sales to individual retailers were kept by the owner himself.

In order to get a picture of monthly sales for Kalomo the figures recorded on the wholesaler stock sheets were adjusted upwards by 13.3%.

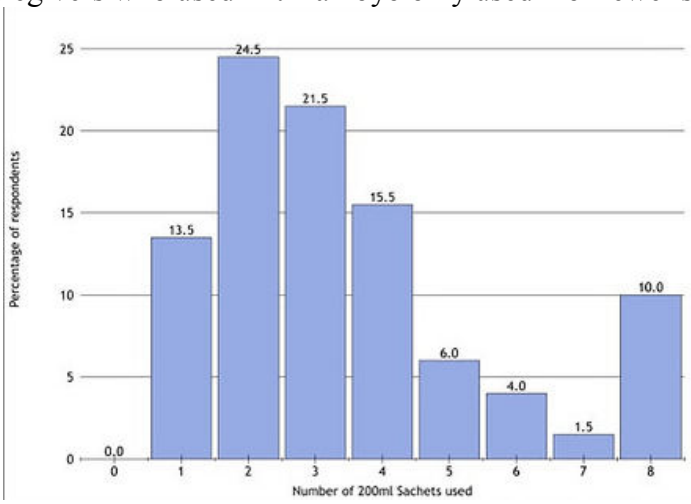
The level of insight and accuracy around sales diminished, from a project perspective, as one moved from the top-end of the value-chain to the bottom. Monthly sales data was most accurate at the manufacturer and wholesaler levels, but not consistently maintained at the retailer level. Thus, there was a limitation in our ability to disaggregate cash-based vs. voucher-based sales on a monthly basis. Only at the end of the project were we able to effectively determine, based on the total kits sold to community-retailers, how many were acquired through vouchers and how many through cash (Total Kit Sales to Retailers – Total Vouchers Redeemed = Cash Sales). Approximately 19% (5000) of sales were cash based, while 81% (21,000) were voucher based.

APPENDIX 5: THE INNOVATION PROCESS - HOW TRIAL FINDINGS HAVE INFLUENCED NEW KIT FORMATS & ONGOING REFINEMENT OF KIT YAMOYO

Innovation is a dynamic process requiring constant evolution. Despite numerous awards and global recognition stemming from the concept of nesting essential medicines in the empty spaces between crated bottles of Coca-Cola, the evidence suggested a need to move in a different direction. Analysis of data from the trial suggested ways in which our model could be improved and achieve potentially greater impact by reducing costs and maintaining key functionalities. While cost is not the only dimension of access, it is indeed an important one. Key findings and refinements are summarized below, and have led to two new kit formats that are now being locally produced and used as part of scale-up efforts in Zambia.

<table>
<tr>
<td>ORS</td>
<td>

85% of caregivers who used Kit Yamoyo only used 4 or fewer sachets.



An additional 10% used all 8 sachets
Assuming those that used all 8 did so because they thought they had to (not because the child was still dehydrated), we can safely assume that 90-95% needed 4 sachets or less.
Reduced number of sachets included from 8 to 4
Encourages combination therapy use, and discourages use of ORS (e.g. saved for use during a future episode) without zinc.
Reduces cost of ORS component by 50%

</td>
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<tr>
<td>Zinc</td>
<td>

During the trial, the zinc (® PedZinc) used in the Kit was being imported from Tanzania, as no locally produced options existed
Working with our pharmaceutical partner, Pharmanova, and the Zambian Medicines Regulatory Authority (ZAMRA), one of the first locally produced zinc products was developed and approved
Human-centered design principles have been applied to try and improve adherence to the 10-day regimen. Will be tested thru ongoing research.
Because zinc is included in kit, no box/packaging or PIL required for blister pack = cost reduction

</td>
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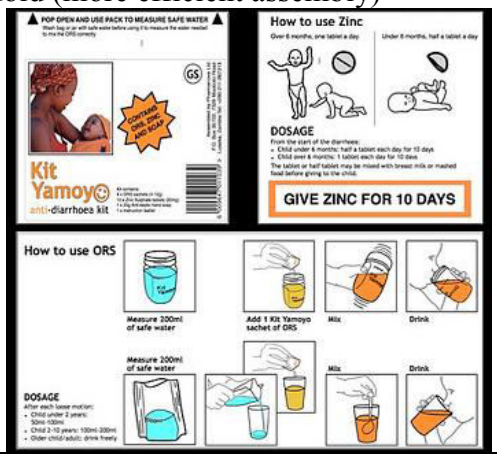
Soap

- Small bar of soap was being imported from India as there was no locally produced small bar of soap
- The only local soap manufacturer in Zambia, Trade Kings, did not produce a small bar
- Discussions with Trade Kings has now resulted in plans to produce a locally manufactured, 25g bar of soap and will help reduce costs further

Leaflet

- Only 30% of Kit users reported using the instructions at endline (higher in Kalomo vs. Katete likely due to differing education levels)
- It was relatively expensive to produce, included instructions in two local languages, and included multiple folds
- Literacy rates of women in rural Zambia are about 54% (DHS, 2014), and although someone may speak a local language, they likely do not read it. If they do read, it is more likely to be in English.
- Focus on graphics, reduce text
- Leaflet also doubles as branding for product (easily changed/adapted for different situations e.g. unbranded public sector version)
- Reduce to single fold (more efficient assembly)



Packaging

- Very few retailers used the empty space between crated bottles of Coca-Cola to transport kits (4-8%); innovative feature not a benefit
- Allowed us to refocus on cost and local production while maintaining key benefits
- Worked with PI Global & Amcor to develop two new formats (i.e. flexi-pack & screw-top) for next phase of work (Kit Yamoyo Transition to scale – KYTS)
- Screw-top is 40% cheaper and can be mad in Zambia now (can retail for 8 kwacha with no top end subsidy)
- Flexi-pack is even cheaper and can retail for 5 kwacha (as in the trial) but with no top end subsidy required and acceptable margins for each player in the value-chain

	Format 2	Format 3	Format 4
4 x 200ml ORS sachets	✔	✔	✔
1 x blister pack of Zinc	✔	✔	✔
1 x 20g bar of soap	✔	✘	✘
1 x 30g bar of anti-bacterial soap	✘	✔	✔
Measuring device	✔	✔	✔
Mixing device	✔	✔	✘
Storage device	✔	✔	✘
Cup	✔	✔	✘

APPENDIX 6: DESCRIPTION OF VARIOUS SOURCES OF PHARMACEUTICALS/PHPs IN ZAMBIA

Outlet Type	Description
Public Health Facility	
Third level hospital	These are government health facilities providing free prescription medicine, medical consultations, and diagnosis. Health centers serve a catchment area of between 10,000 (rural) to 50,000 (urban) residents. They are staffed by a nurse or clinical officer. First-level hospitals accept referrals from local health centers and health posts. They serve populations of between 80,000 and 200,000 people with surgical, obstetric and diagnostic services. At the provincial level, second-level hospitals typically offer services in internal medicine, gynecology, psychiatry and intensive care. Third-level hospitals serve a catchment of 800,000 people and expand upon provincial level services, while also serving as training and research institutions.
Second level hospital	
First level hospital	
Hospital affiliated center	
Urban health center	
Rural health center	
Health post	
Part One Pharmacy	
Part one pharmacy	Pharmacies that are licensed by the Zambian Medicines Regulatory Authority (ZAMRA) and sell prescription medicine at a commercial rate. Part One pharmacies are manned by pharmacists and qualified health practitioners. They sell all classes of medicines. In addition to being regulated by the PRA, they are also required to have a trading license from the local council. These pharmacies may also sell cosmetics. Only found in major centers.
Drug Shop	
Drug shop	Drug shops sells medicines at a commercial rate, but differ from pharmacies in a number of aspects: 1) Drug stores are usually smaller than pharmacies; 2) they are not regulated by the Zambian Medicines Regulatory Authority (ZAMRA), and instead are licensed by the local government board (however, an unknown proportion operate without a license); 3) they are only permitted to sell over the counter medicines; 4) they are not guaranteed to be manned by qualified health dispensers/ practitioners, and are sometimes manned by relatives of qualified health dispensers or someone with only basic education or knowledge about

	medicines. Not typically found in rural areas.
Private Health Facility	
Private hospitals	Private hospitals sell medicines at a commercial rate and are manned by qualified health dispensers/practitioners, who are registered with the medical council. These facilities are regulated by the Zambian Medicines Regulatory Authority (ZAMRA). They have a hospital license and can admit patients for more than 48 hours.
Private clinic	Private clinics sell medicines at a commercial rate and are manned by qualified health dispensers/practitioners, who are registered with the medical council. As with private hospitals, they are regulated by the Zambian Medicines Regulatory Authority (ZAMRA). Private clinics have a clinic license, and differ from hospitals in that they can admit patients for a maximum of 48 hours.
Surgery	Surgeries are also manned by qualified health practitioners who are registered with the medical council. They have a clinic license and offer certain specialized services, but they are not allowed to admit patients. They are most common in urban areas.
Grocery Store	
Grocery store*	Small businesses that sell fast moving consumer goods including food, beverages, and household products. These outlets commonly sell antipyretics, but may have the potential to sell other types of PHPs.
Other	
Kiosk*	Small businesses, made from temporary wooden structures, which sell fast moving consumer goods. They may also sell medicines. Kiosks are usually found near schools, colleges and universities.
Kantemba*	These are similar to kiosks but have a more permanent structure. They are twice the size of a phone booth with walls made from metal.
Super/Mini market or petrol station	Express stores at filling stations. Small businesses which sell general groceries; they may stock some medicines such as such as antipyretics or cough syrups.
Container	This is a shipment container that has been turned into a shop. They have commodities that can also be found in grocery stores but

	may also sell over the counter medicines. Containers need to obtain a trading license from the local council. These are typically found along major roadways near towns.
Mobile provider	These are street hawkers who sell a variety of items, which may include medicines. They typically operate in residential areas and at road junctions. In residential zones, hawkers mostly target low income and rural areas. In urban zones, they may have a hawker's license under the local council.
Other	Other outlet types not fitting into any of the aforementioned outlet types - largely market stands and stalls.

Source: Palafox B, Patouillard E, Tougher S, Goodman C, Hanson K, Mpasela F, O'Connell K and the ACTwatch Study group. 2012. ACTwatch 2009 Supply Chain Survey Results, Zambia. Nairobi: ACTwatch project, Population Services International.

* Outlet types that form the basis of this study highlighted in green

APPENDIX 7: EXAMPLE OF HOUSEHOLD SURVEY

Household Survey - Endline

Please note that further changes were made to this survey upon entry into ODK. This is a near final version, however skip patterns, images, minor wording changes, etc. may have changed since this version.

Note: Module response sequences depend on respondent. Each respondent will not have to go through every module:

Caregivers with a child who had diarrhea in the 2 weeks preceding survey

Module Sequence: **1, 2, 3 → 6 → 5**

Caregivers without a child who had diarrhea in the 2 weeks preceding survey

Module Sequence: **1, 2, 4 → 6 → 5**

Caregivers who used Kit Yamoyo

Children w/ diarrhea in past 2 weeks: 1, 2, 3, 4, 6, 5

Children w/out diarrhea in past 2 weeks: 1, 2, 4, 7, 6, 5

COTZ- HOUSEHOLD SURVEY–Endline **QID: _____**

Interviewer: Ask to speak to head of household. If head of household is not available, ask to speak to a household member who can assist. Read the following:

Good day, I am (insert name). I am representing UNICEF, Keepers Zambia Foundation, and RuralNet Associates as part of a research partnership here in Zambia, for a study approved by Ministry of Health. I am part of a team interviewing people about health products. The information will be used to improve health products and services for people like you.

Can you please tell me if there any children between 6 and 59 months old who live in this household? These are **children born on or after 18 August 2008 and before February 17 2013**.

If no, thank the respondent and move to next household.

If Yes, How many children in this household are between the ages of 6 and 59 months?

CONTINUE

Your household has been selected to participate in this study randomly. The information gathered here and your details will be kept confidential, and you do not have to answer any questions that you do not want to. Your participation in the study is voluntary and you will not be affected in any way if you decide not to participate. It is your choice. If you agree to help, I will ask you a series of questions related to your access to health products and services. We will use this electronic tablet to enter your responses to our questions. The interview will take about 1 hour.

I would first like to ask some questions about your household, and then ask about diarrhea in children to the main caregiver of a child within your household. The answers will help us to learn more about opinions and experiences concerning diarrhea in children, and will be used to improve health products and services for people like you.

Do you have any questions? You may contact Stephen Tembo of RuralNet Associates [give business card if they would like] if you have any further questions or concerns related to this work. You may contact the Ethics Committee which approved this study about any problems or concerns as well. Would your household like to help by participating in the study?

If "No", STOP.

Interviewer: Can I ask why you would **not** like to participate in this survey?

Not interested 1

Busy 2

Other 3

_____

Thank the respondent and move to next household.

If yes, get signature and administer screening matrix in tablet and say: "Okay, let's begin".
MOVE TO SURVEY.
_____(Signature of head of household/assistant)
_____(Date)
_____(Signature of caregiver) _____(Date)

Q001. Individual code	Please give the FIRST NAME ONLY of the children between the ages of 6 and 59 months who usually live in this home. These are **children born on or after 18 August 2008 and before February 17 2013**.	Q002. What age is (NAME)? Exact number of months MONTHS	Q003. Please give the FIRST NAME ONLY of the child's primary caregiver.	Q004. Please give the age of the child's primary caregiver. YEARS	Q005. Is the caregiver around? 0 No 1 Yes	Q006. Has (NAME) had diarrhea in the last 2 weeks? (Verify with caregiver that diarrhea = 3 or more loose or watery stools per day) 0 No 1 Yes 2 Don't know
01		**[__][__]months Give legend: 12 months = 1yr**		**[__][__]**	**0 1 2**	**0 1 2**

		24 months = 2 yrs 36 months = 3 yrs 48 months – 4 yr				
02						
03						
04						
05						
06						

INTERVIEWER:

- **If no caregivers are aged 15 years or older, thank the respondent and move to next household.**
- **If there is a caregiver aged 15 years or older in the house, select 1 caregiver aged 15 years or older to participate based on the sampling strategy below.**
- **Caregiver Sampling Order:**
    - **Caregiver who is present**
    - **Main caregiver of Child between 6 and 59 months of age with diarrhea in the past 2 weeks who is available (verify with caregiver that diarrhea = 3 or more loose or watery stools in a day)**
    - **Main caregiver of Child between 6 and 59 months who is available**
    - **If multiple caregivers with children between 6-59 months who had diarrhea, and are available, select alphabetically by first name**
- **Reference child sampling order:**
    - **If the caregiver selected has more than one child between 6-59 months of age with diarrhea, select the reference child alphabetically by first name**
- **If the caregiver selected is different from the initial person you spoke with, get them to sign the informed consent as well.**
- **Diarrhea is defined as *3 or more loose or watery stools in one day. Review this definition with caregiver to make sure you are talking about the same thing.**

QUESTIONNAIRE FOR MOTHERS/CARERS - baseline

Module 1: QUESTIONNAIRE IDENTIFICATION DATA & FILTERS
001 Question for Care givers : Do you agree to participate in this survey ?
YES → Move on to Questions below. Ensure that Caregiver has signed the consent form.
NO→ Terminate Interview
002 Questionnaire Identification Number (From your assigned block of Ids)
|__|__|__|__|__|__|
003 SiteNumber_____
We would like to start by asking some background questions about your household.
004 Name of head of household (First and Last Name) _____

Q1001.	Enumerator's name			
Q1002.	Supervisor Name			
Q1003.	Province Code	1. Southern 2. Eastern		
Q1004.	District Code	1. Kalomo 2. Katete 3. Monze 4. Petauke		
Q1005.	What is the name of your Village/Community?			
Q1006.	Time Started:_____			
Q1007.	Respondent's relationship to head of household	Head of Household Spouse Child Niece/Nephew Parent Other (specify)_____	1 2 3 4 5 999	
Q1008.	Sex of respondent	Male Female	1 2	
Q1009.	How old are you? **(Interviewer: Record age in completed years)**	**[_____] Years**		

NO	Questions & Filters	Responses		Skip To
Q1010.	Sex of Head of Household	**Female** **Male**	**1** **2**	**If answer to Q1007 is 1**

				(respondent is head of household skip this question)
Q1011.	What is the highest level of school successfully completed by the **head of household**? **Interviewer, please note the following equivalent standards and grades for:** **Sub A to standard 3 = Grades 1 - 5** **Standards 4 to 6 = Grades 6 - 8** **Form 1 to 3 = Grades 8-10** **Form 4 to 5 = Grades 11- 12**	Grade 1 to 4 Grade 5 to 7 Grade 8 to 9 Grade 10 to 12 Higher learning None Don't know Other Specify_____	1 2 3 4 5 6 888 999	**If answer to Q1007 is 1 (respondent is head of household skip this question)**
Q1012.	How old is the head of household? (in completed years)	**[_____] Years** Don't Know	**888**	**f answer to Q1007 is 1 (respondent is head of household skip this question)**
Q1013.	What is the highest level of school **you** have successfully completed? **Interviewer, please note the following equivalent standards and grades for:** **Sub A to standard 3 = Grades 1 - 5** **Standards 4 to 6 = Grades 6 - 8** **Form 1 to 3 = Grades 8-10** **Form 4 to 5 = Grades 11- 12**	Grade 1 to 4 Grade 5 to 7 Grade 8 to 9 Grade 10 to 12 Higher learning None Don't know Other Specify_____	1 2 3 4 5 6 888 999	
Q1014.	What was the main activity of the head of household during the past month?	Unemployed Housewife Student	1 2 3	→Q1016 →Q1016 →Q1016

		Retired/Pensioner Farmer/Gardener/Fisher Civil servant (government worker) Formal private company employee Informal small business owner Informal Small businessemployee Piece worker Brick layer/builder Teacher Other Specify _____	4 5 6 7 8 9 10 11 12 999	→Q1016 →Q1016
Q1015.	What is the nature of this work? That is, is it permanent, temporary, or occasional?	Permanent Temporary/Occasional Don't Know Other (specify)_____	1 2 888 999	
Q1016.	How many **hectares** of farmland does your family/household own? **1 Lima or ¼ hectare = half a football pitch** **1 hectare = 2 football pitches** **1 acre = 0.4 hectares** **1 lima = 0.25 hectares**	[_____] hectares Don't know	**888**	
Q1017.	How many of the following animals does your household own: Goats? Sheep? Cows?chickens?pigs? (***Interviewer: READ LIST AND RECORD RESPONSE FOR EACH ITEM. If none, enter « 00 ». If 96 or more, enter « 96 ». If number is not known, enter « 888»***).			

		A Goats		
		B Sheep		
		C Cows/oxen		
		D Chickens		
		E Pigs		

Q1018.	Do you own or rent your home?	Own Rent Family/relative Institution (e.g. church, company, govt) Other (specify)_____	1 2 3 4 999	
Q1019.	How many rooms are in your dwelling? **INTERVIEWER: DWELLING IS DEFINED AS THE INDIVIDUAL UNIT THAT THE CAREGIVER LIVES IN.** **NOTE: THIS IS DIFFERENT FROM A FAMILY PROPERTY WITH MULTIPLE UNITS**	Number of Rooms [__][__] Don't Know	 888	
Q1020.	**(INTERVIEWER: OBSERVE AND REPORT.**	Earth/Sand/ Mud/Dung	1	

	IF UNCLEAR READ LIST IF NECESSARY) What is the main material of the floor in the dwelling where your household lives?	Parquet or Polished Wood Carpet Ceramic Tiles Cement/Concrete Other Specify____	2 3 4 5 999	
Q1021.	**(INTERVIEWER: OBSERVE AND REPORT. IF UNCLEAR READ LIST IF NECESSARY)** What is the main material of the roof in the dwelling where you household lives?	Concrete/Cement Metal Sheet Clay Straw/grass Asbestos Other (specify)_____	1 2 3 4 5 999	

Q1022.	Does your household have: **(INTERVIEWER: READ LIST AND RECORD RESPONSE FOR EACH ITEM)**			Yes	No	
		A	Electricity	1	2	
		B	Radio	1	2	
		C	Television	1	2	
Q1023.	Does any member of your household own: (INTERVIEWER: READ LIST AND RECORD RESPONSE FOR EACH ITEM)			Yes	No	
		A	Bicycle	1	2	
		B	Motorcycle/Scooter	1	2	
		C	Car or Mini-Truck	1	2	
		D	Mobile Phone	1	2	
Q1024.	What is the main source of drinking water for members of your household? **[SINGLE RESPONSE]**	Piped water in residence/house Piped water in public tap Protected well Unprotected well Borehole River, stream, canal, or surface water Rainwater Other (specify)_____	1 2 3 4 5 6 7 999			
Q1025.	What kind of toilet do **most** members of your household use? [**SINGLE RESPONSE**]	Own flush toilet Shared flush toilet Pit latrine with concrete slab Pit latrine without slab/open pit Ventilated improved pit (VIP) latrine Integrated Latrine (toilet and hand-washing together) None/Bush Other (specify)_____	1 2 3 4 5 6 7 999			
Q1026.	What do you use as your main source of fuel for cooking in this household? [**SINGLE RESPONSE**]	Kerosene Electricity Coal charcoal	1 2 3 4			

		Wood/Straw Other (specify)_____	5 999	
Q1027.	What are the main health issues for children under 5 yrs of age in your community? **[MULTIPLE RESPONSES ALLOWED - DO NOT READ LIST]**	Diarrhea Malaria Pneumonia Malnutrition Measles Eye disease Coughing Epilepsy/Fits Don't know Other (Specify)_____	1 2 3 4 5 6 7 8 888 999	

Module 2: Child Diarrhea Status→ Make change of module obvious in tab. Ensure Heading shows up. Delete these comments in paper version to be printed.

	Questions/Filters	**Codes/Responses**		**Skip To**
Q2001.	What is the first name of the selected child between 6 and 59 months of age **Selected using sampling strategy: first precedence – child with diarrhea in last 2 weeks; 2nd precedence - alphabetical**	Name: _____		
Q2002.	Please circle the sex of (NAME).	Male Female	1 2	
Q2003.	What is (NAME's) date of birth?	Day [_____] Month [_____] Year [_____] Don't Know	 888	
Q2004.	What is your relationship with (NAME) ? INTERVIEWER: WE ARE ASKING WHAT IS THE CAREGIVER'S RELATIONSHIP TOTHECHILD	Mother Father Grandmother Grandfather Auntie Sister/brother Other (specify)_____	1 2 3 4 5 6 999	
Q2005.	Thinking back over the past 3 months, have you seen or	Yes No	1 2	 →2007

	heard any messages about treatment for diarrhea?			
Q2006.	Where did you hear/see the message(s) about treatment for diarrhea? **Interviewer: Multiple responses allowed. Note all that apply. Do not read list.**	Radio Television Community education session/health talk Community health worker Health clinic nurse/doctor/clinical officer Neighbor/friend Newspaper School Church Banner/poster/etc Private shop/Community Retailer/Intemba Kit Yamoyo Promoter Other specify)_____	1 2 3 4 5 6 7 8 9 10 11 12 999	→2007 →2007 →2006 a →2006 a →2006 a →2006 a →2006 a →2007 →2006 a →2006 b →2006 a →2006 a →2007
2006.a	Was the person delivering the message wearing a t-shirt that looked like this? SHOW PICTURE OF ORANGE PROMOTERS T-Shirt& RED SHOPKEEPER T-SHIRT (Include on tablet if possible)	YES NO Don't remember	1 2 3	→2007 →2007 →2007
2006.b	Was it one of these posters? **Show Picture of Kit Yamoyo promotional posters (include on tablet if possible)**	YES NO Don't remember	1 2 3	
Q2007.	Has (NAME) had diarrhea	Yes	1	→Mod

	in the last 2 weeks? **Interviewer: Diarrhea is defined as 3 or more loose or watery stools in one day. Review that definition with caregiver.**	No	2	3 →Mod 4

Module 3: Children under 5 with diarrhea in past 2 weeks

Q3001.	How many days ago did the diarrhea start? ***(Interviewer: If the same day, record '00.')*** ***Probe: try to help them remember the exact number of days, as opposed to saying 1 week or 2 weeks.***	**[__][__] days** **Don't Know**	 **888**	
Q3002.	For how many days did the child have diarrhea? **(*Interviewer: if the child still has diarrhea, ask "*How many days has the child had diarrhea*")***	**[__][__]days**		
3002aa	When (NAME) had diarrhea over the past 2 weeks, on average, how many loose or watery stools did he/she have **per day**?	[__][__] loose or watery stools		
3002a	Has the child had diarrhea on and off for more than 4 weeks?	Yes No Don't Know	1 2 888	 **→3003** **→3003**
3002b	How long has the child had diarrhea on and off for? **1 Month = 4 weeks** **2 Months = 8 weeks** **3 Months = 12 weeks**	_____ weeks Don't Know	 888	

	4 Months = 16 weeks			
Q3003.	Has (NAME) also had a fever in the last 2 weeks?	Yes No Don't Know	1 2 888	
Q3004.	Did (NAME) have any blood in the stool when he or she had diarrhea in the last 2 weeks?	Yes No Don't know	1 2 888	
Q3005.	How much fluid/liquid was (NAME) given to drink during the recent episode of diarrhea? Was he or she given less than usual to drink, about the same amount, more than usual to drink, or nothing to drink? ***(Interviewer: If "less," probe: Was (NAME) given much less than usual to drink or somewhat less?)***	Much less Somewhat less About the same More Nothing to drink Don't know	1 2 3 4 5 888	
Q3006.	Did (NAME) breastfeed during the recent episode of diarrhea? **(*Interviewer: If Yes, Probe: More? Less? Or about the same?*** ***If No, find out why – see responses)***	**<u>YES</u>** Breastfed more Breastfed less Breastfed about the same **<u>No</u>** Never breastfed Stopped breastfeeding due to diarrhea Does not breastfeed anymore/weaned/too old Other (Specify) Don't know	 1 2 3 4 5 6 99 9 888	
Q3007.	When (NAME) had diarrhea, was he or she given less than usual to **eat,** about the same amount, more than usual, or nothing?	Much less Somewhat less About the same More Nothing to eat Don't know	1 2 3 4 5 888	

	Interviewer: If "less," probe: Was child given much less than usual to eat or somewhat less?			
Q3008.	Do you know what ORS is? (**Interviewer: refer to it in different ways – local name (Manzi yamoyo), Oral Rehydration Salts, and *show image of local ORS packets on screen noting that they sometimes look like this.***	Yes No	1 2	**→3017 A**
3008b	In the past **3 months** have you heard any messages about ORS?	Yes No	1 2	**→3009 a**
Q3009.	Have you ever heard any messages about ORS?	Yes No	1 2	**→Q3010**
Q3009a	Where did you hear/see the message(s) about ORS? **Interviewer: Multiple responses allowed. Note all that apply. Do not read list.**	Radio Television Community education session/health talk Community health worker Health clinic nurse/doctor/clinical officer Neighbor/friend Newspaper School Church Banner/poster/etc Private shop/Community Retailer/Intemba Kit Yamoyo Promoters Other specify)_____	1 2 3 4 5 6 7 8 9 10 11 12 99 9	→3010 →3010 →3009 b →3009 b →3009 b →3009 b →3009 b →3010 →3009 b →3009 b →3009c. →3009

				b →3009 b →3010
3009.b	Do you remember if the person delivering the message was wearing a t-shirt that looked like this? SHOW PICTURE OF ORANGE PROMOTERS T-Shirt (Include on tablet if possible)	YES NO Don't remember	1 2 3	**→3010** **→3010** **→3010**
3009.c	Was it one of these posters? Show Picture of Kit Yamoyo promotional poster (include on tablet if possible)	YES NO Don't remember	1 2 3	
Q3010.	Please tell me if you agree or disagree with each of these statements. **Interviewer: Read this list.**	Ag Dis DK ORS is medicine that gives good health 1 2 888 ORS is a treatment for diarrhea 1 2 888 ORS stops Diarrhea 1 2 888 My child does not like the taste of ORS 1 2 888 ORS prevents Dehydration 1 2 888		
Q3011.	Can you describe the process of how to make ORS Solution in as detailed a way as possible?	Mix contents of ORS package with water Ensure water is clean/Purify water Ensure proper measurement of water	1 2 3 4	

	(multiple answers allowed. check all that are mentioned by caregiver. Do not read responses. Only check boxes that are mentioned by respondent)	Wash hands prior to preparing Respondent explains how to use Kit Yamoyo Sprinkle over food Swallow Powder Don't know Other (specify)_____	 5 6 7 88 8 99 9	
Q3012.	Do you think ORS is effective in treating diarrhea?	Yes No Don't know	1 2 888	**→3013** **→3014** **→3015**
Q3013.	Why do you think ORS is effective in treating diarrhea? ***(Do not read responses. Multiple responses allowed. Only check boxes that are mentioned by respondent)***	Diarrhea stops quickly Child recovers quickly Child regains appetite Prevents dehydration Don't know Other (specify)_____	1 2 3 4 888 999	**→3015** **→3015** **→3015** **→3015** **→3015** **→3015**
Q3014.	Why don't you think ORS is effective in treating diarrhea? ***(Do not read responses. Multiple responses allowed. Only check boxes that are mentioned by respondent)***	It only prevents dehydration It is only for giving strength Diarrhea does not stop soon/diarrhea continues Child doesn't like the taste Too hard to administer Don't know Other (specify)_____	1 2 3 4 6 888 999	
Q3015.	Do you plan on using ORS the next time your under 5 child has diarrhea?	Yes No Don't know	1 2 888	
Q3016.	Was [NAME] given any ORS solution to drink since he or she started having	Yes No Don't know	1 2 888	**→3017** **→3017A** **→3017A**

	diarrhea? **(Interviewer: Show examples of ORS – Images on tablet and probe: "These are some local examples of ORS, did you give any of these?")**			
Q3017.	Which ORS product(s) was given to (NAME)? ***(Interviewer: Multiple responses allowed. If they don't know, you can show them the poster with samples of local products (ORS packets and the actual kit yamoyo sachet, and ask respondent to select any/all used during the recent episode of diarrhea.)*** ***If more then one answer is selected, confirm that they used two different types of ORS during the most recent episode of diarrhea***	GRZ (Health Center) From Kit Yamoyo Other from Private shop (eg. Novalyte)? Don't know	**1** **2** **3** **88** **8**	**→Mod 7**
3017A	Thinking back over the **past 6 months**, have you heard a message/received information about an anti-diarrheal kit called Kit Yamoyo? **Interviewer: Show Image of Kit Yamoyo**	YES NO Don't Know	1 2 888	**→3017 C; and If also NO to 3016 skip to 3031 →3017 C**
3017B	Did you use the Kit Yamoyo to treat [NAME] when he/she had diarrhea in the past 2 weeks?	YES NO Don't Know	1 2 888	**→Mod 7**
3017C	Have you ever used the Kit Yamoyo to treat any of your	YES NO	1 2	**→3017C 2**

	children under-5 with diarrhea?	Don't know	888	**→3017 D →3017 E**
3017C2	If you used the Kit Yamoyo previously to treat diarrhea in one of your children, but not during the most recent episode, why did decide not to buy one during the most recent episode?	Kit is too expensive Kit was not available at my local shop I prefer to go to the health center I did not have a voucher I did not know I could buy it Don't Know Other, Specify	1 2 3 4 5 88 8 99 9	**ALL to Mod 7**
3017D	If no, why did you not use the Kit Yamoyo to treat your child's diarrhea? **Interviewer. Do not read list. Multiple responses allowed.**	Child has not had diarrhea Kit is too expensive Kit was not available at my local shop I prefer to go to the health center I have not heard about it/Do not know what it is Don't Know Other, Specify	1 2 3 4 5 88 8 999	**If NO to 3016 skip to 3031. Rest to next question.**
3017E	How many days after the diarrhea began did (NAME) first **get ORS**? **Interviewer: if same day mark '00'**	(___) Don't Know	 88 8	
Q3018.	How many packets of ORS did you prepare for (NAME) during the episode of diarrhea? **If they say one, probe: did you use the whole packet?**	_____ Don't Know	 88 8	
Q3019.	Did you use ordinary water or did you use treated water when you prepared	Ordinary (Non-purified) Water Treated Water (chlorine) Treated Water (Boiled)	1 2 3	

	the ORS?	Other (specify)_____	99 9	
Q3020.	How much of the ORS packet/sachet did you use each time you prepared the ORS? **(*Interviewer: If they don't know how to respond, you may give examples from the list*)**	Entire contents of packet Half of the packet Less than half Other Specify_____	1 2 3 99 9	
Q3021.	What quantity of water did you mix the ORS with each time you prepared the solution? **Interviewer: If they don't know the particular metric measurement, probe as to what type of container they used to measure the amount of water. Do not read list of responses.**	Used1 standard household drinking cup/mug/glass Used Kit Yamoyo Container Used a large bottle of cola/soda (full) 200Milliliters 750 Milliliter 1 Liter 2 Liters 2.5 liter container (full) Don't Know Other Specify_____	1 2 3 4 5 6 7 8 88 8 99 9	
Q3022.	How many days did you give the child the ORS?	**[_][_]**		
Q3023.	How often did you give the ORS solution to (NAME)? ***(Interviewer: Read the list and ask respondent to select one response.)***	Frequently After each liquid stool Morning, mid-day, and night Whenever the child wanted it Don't know Other (specify)_____	1 2 3 4 88 8 99 9	
Q3024.	From where was the ORS originally obtained?	Health center/clinic/hospital Community health worker Private pharmacy Neighbor/friend/family member Traditional Healer NGO/ Faith-based organization/CBO Private shop/Community Retailer/Intemba	**1** **2** **3** **4** **5** **6** **7**	 **→Q3026** **→Q3026** **→Q3026** **→Q3026** **→Q3026**

		Don't know Other (specify)_____	**888** **999**	**→Q3026** **→Q3026** **→Q3026**
Q3025.	From which health facility did you obtain the ORS?	[_____]		
3025A	How much did you spend on transport to get to the health center? **If they spent nothing to get there, put "0"**	[_____]Kwacha Don't know	 **888**	
3025B	How much did you spend on food and drinks during your trip to the health center? **If they spent nothing to get there, put "0"**	[_____]Kwacha Don't know	 **888**	
3025C	What other expenses if any, did you have during your trip to the health center?	Medicines User fee at clinic None Other, Specify_____	**1** **2** **3** **888**	 **→3026**
3025D	How much did you spend on this?	[_____] don't know	 888	
Q3026.	Did you pay for the ORS?	Yes No Don't know	**1** **2** **888**	 **→3028** **→3028**
Q3027.	How much did you pay? **Put currency (Kwacha)**	(_____) Kwacha		
Q3028.	What do you think of the price of ORS? **Interviewer: Read options and ask respondent to select one response.**	Not expensive Affordable Expensive Too expensive No opinion Don't know	1 2 3 4 5 888	

Q3029.	How far from your household was the location the ORS was obtained from? **(Interviewer: Ask for response in Km)**	[_____] km Don't know	 **888**	
Q3030.	How long did it take to walk there from your home? **Interviewer: If they say they did not walk, ask them how long it would take to walk there.**	Minutes [_____] Don't know 1 hour = 60 mins 2 hours = 120 mins 3 hours = 180 mins 4 hours = 240 minutes	 **888**	
Q3031.	Was (NAME) given a home-prepared sugar-salt solution (SSS) during his/her recent episode of diarrhea? **Inteviewer: Use the local term(s) for the sugar-salt solution (as distinguished from purchased ORS). Explain 1 teaspoon of salt to 6 teaspoons of sugar in a Liter of water.**	Yes No Don't know	1 2 88 8	**→3033** **→3034**
Q3032.	How often did you give the home-prepared sugar-salt solution to (NAME)? **Interviewer: Read the list and ask the respondent to select one response.**	Frequently After each liquid stool Morning, mid-day, and night Whenever the child wanted it Don't know Other (specify)_____	1 2 3 4 888 999	
	If Q3016=2 (NO) AND Q3031=2 (NO) then go to Q3033. Otherwise, go to Q3034.			

Q3033.	***Interviewer: If the caregiver did not provide either ORS or SSS to the child, ask*** "why did you not give (NAME) either ORS or home-prepared sugar-salt solution?" ***[Interviewer: Do not read list. Multiple responses allowed.]***	Child not seriously ill Could not find ORS/SSS to buy Products too costly Child/Mother does not like Didn't know about ORS/SSS Health center did not have any No nurse/doctor/health staff available at clinic Gave other medicine Didn't know how to make SSS Forgot about ORS/SSS Other (specify)_____	1 2 3 4 5 6 7 8 9 10 999	
	Now I'd like to ask a few questions about diarrhea <u>treatments</u>.			
Q3034.	Did you seek **advice** for the diarrhea?	Yes No	1 2	**→Q3036**
Q3035.	Where did you receive the main advice?	Health center/clinic/hospital Community health worker Private pharmacy Neighbor/friend/family member Traditional Healer NGO/ Faith-based organization/CBO Private shop/Community Retailer/Intemba Kit Yamoyo Promoter Don't know Other (specify)_____	1 2 3 4 5 6 7 8 888 999	
Q3036.	Did you seek **<u>treatment</u>** from someone outside the home for the diarrhea?	Yes No	1 2	**→Q3039**
Q3037.	How many days after the diarrhea began did you first **<u>seek</u> treatment**? **Interviewer: If the same day, record '00.'**	**[_][_]**		
Q3038.	Where did you **<u>receive</u>** the		1	

	treatment for (NAME)? **(Interviewer: Do not read list. Multiple responses allowed)**	Health center/clinic/hospital Community health worker Private pharmacy Neighbor/friend/family member Traditional Healer NGO/ Faith-based organization/CBO Private shop/Community Retailer/Intemba Don't know Other (specify)_____	2 3 4 5 6 7 888 999	
Q3039.	How many days after the diarrhea began did (NAME) first **get treatment**?	**[_][_]** **Other, Specify_____**		
Q3040.	Was (NAME) given anything other than ORS or a home-prepared treatment to treat the diarrhea? **Interviewer: Probe, We want to know any other treatments which were given to treat the child, aside fromORS and SSS.**	Yes No Don't know	1 2 888	→Q3042 →Q3042
Q3041.	Can you tell me or show me what treatments were given to (NAME)? **Interviewer: If the respondent is not sure which products were given, show image with local options. Multiple options allowed. Click all that apply.** **Probe: Anything else?**	Kit Yamoyo Zinc Antibiotic (e.g. flagyl) Anti-diarrheal Anti-malarial Other pill/syrup Intravenous fluid/drip Vitamins Herbal/traditional remedy, specify___ Don't know Other (specify)_____	1 2 3 4 5 6 7 8 9 888 999	
Q3042.	Have you ever heard about zinc as a treatment for childhood diarrhea?	Yes No	1 2	 **→3073**

	Interviewer: Show images of zinc examples to respondent (PedZinc, blister pack, Health Center Zinc)	Don't know	888	**→3073**
Q3043.	Can you tell me what you know about zinc? **Interviewer: Multiple responses allowed. Do not read list.** **Probe: anything else?**	Treatment for diarrhea Needs to be taken with ORS/ORT Makes child stronger Helps prevent future episodes of diarrhea Reduces duration and severity of diarrhea Nothing Other (Specify)_____	1 2 3 4 5 7 999	
Q3044.	Thinking back over the last 3 months, have you heard any messages or received information about zinc?	Yes No Don't know	1 2 888	**→3048** **→3048**
3044a	Where did you hear/see the message(s) about zinc? **Interviewer: Multiple responses allowed. Note all that apply. Do not read list.**	Radio Television Community education session/health talk Community health worker Health clinic nurse/doctor/clinical officer Neighbor/friend Newspaper School Church Banner/poster/etc Private shop/Community Retailer/Intemba Kit Yamoyo Promoters Other specify)_____	1 2 3 4 5 6 7 8 9 10 11 12 999	→3047 →3047 →3045 →3045 →3045 →3047 →3045 →3045 →3046 →304

				5 →3045 5 →3045 7
Q3045.	Was the person delivering the message wearing a t-shirt that looked like this? **SHOW PICTURE OF ORANGE PROMOTERS T-Shirt and RED SHOPKEEPER T-SHIRT(Include on tablet if possible)**	YES NO Don't remember	1 2 3	→3047 →3047 →3047
Q3046.	Was it one of these posters? **Show Picture of Kit Yamoyo promotional posters (include on tablet if possible)**	YES NO Don't remember	1 2 3	
Q3047.	What information did you get from the message(s) that you heard? **Interviewer: Multiple responses allowed.** **Probe: anything else?**	Zinc reduces the duration of the diarrheal episode Zinc reduces the severity of diarrhea The risk of new episode in the future is reduced Zinc is available in health centers Zinc should be taken with ORS/ORT A complete 10-day dose should be administered Zinc is an appropriate treatment for diarrhea Zinc is a micronutrient Zinc is used for malnutrition Don't know Other (specify)_____	1 2 3 4 5 6 7 8 9 888 999	
Q3048.	Did anyone recommend you use zinc to treat the diarrhea?	Yes No Don't know	1 2 888	→Q3050 →Q3050
Q3049.	If yes, who recommended zinc? ***(Interviewer: Do not read list. Mark only one***	Health center/clinic/hospital Community health worker Private pharmacy Neighbor/friend/family member	1 2 3 4 5	

	answer).	Traditional Healer NGO/ Faith-based organization/CBO Private shop/Community Retailer/Intemba Kit Yamoyo Promoter Don't know Other , (specify)_____	6 7 8 888 999	
Q3050.	Did anyone give (NAME) a zinc product?	Yes No Don't know	1 2 888	**→3052** **→Mod 6**
Q3051.	If NO, can you tell me why you did not give your child zinc to treat the diarrhea?	Never heard of zinc Did not know where to buy Zinc is too expensive Used another product I had confidence in Don't think it works I had it, but didn't know I was supposed to use it Other (specify)_____	1 2 3 4 5 6 999	**From here skip Q3073**
Q3052.	Which type of zinc product was (NAME) given? **Interviewer: Show examples of any local zinc products**	Tablets from health center Tablets from Kit Yamoyo (PedZinc) Syrup Don't know Other, Specify_____	1 2 3 888 999	→3056 →3056 →3056
Q3053.	How many zinc tablets did you receive?	(_____) Don't know	888	
3053B	How many zinc tablets did you give [NAME] per day?	(_____) Don't know	888	
Q3054.	How many days did you give zinc to (NAME)?	(_____) Don't Know	888	If greater than 9 go to 3056
Q3055.	**Interviewer: If less than**	Child was cured Child would not take zinc treatment	1 2	

	10 tablets ask: Was there a reason (NAME) took less than 10 tablets? **Interviewer: Do not read list. Multiple responses allowed.**	Child vomited treatment Needed treatment for another person Wanted to save remaining treatment for future illness Did not know child needed to take entire treatment Thought I needed to give zinc only along with ORS Child still taking the treatment Other (specify)_____	3 4 5 7 8 9 999	
Q3056.	Where did you obtain the zinc product? **Interviewer: Mark only one answer.**	Health center/clinic/hospital Community health worker Private pharmacy Neighbor/friend/family member Traditional Healer NGO/ Faith-based organization/CBO Private shop/Community Retailer/Intemba Don't know Other (specify)_____	**1** **2** **3** **4** **5** **6** **7** **888** **999**	
Q3057.	How far from your household was the location the zinc was obtained from? **(Interviewer: Ask for response in Km)**	[_____] km Don't know	 **888**	
Q3058.	How long did it take to walk there from your home? **Interviewer: If they say they did not walk, ask them how long it would take to walk there.**	Minutes [_____] Don't know 1 hour = 60 mins 2 hours = 120 mins 3 hours = 180 mins 4 hours = 240 minutes	 888	
Q3059.	What was your main reason for choosing this source of supply? **Interviewer; Mark only one answer. Do not read list.**	Price Easily accessible Quality of care Most knowledgeable source Only place I know to get it Other (Specify)	1 2 3 4 5 999	
Q3060.	Did you give (NAME) ORS or	Yes	1	→Q306

	SSS along with the Zinc?	No	2	2
Q3061.	What was the primary reason you did not give ORS or SSS along with zinc? **Interviewer: Do not read list. Mark only one response.**	Did not know it should be given together Did not have ORS Don't think ORS is effective Didn't have ingredients for SSS/ORT Other (specify)_____	1 2 3 4 999	
Q3062.	What dose of zinc per day was given to (NAME)?	Half tablet 1 whole tablet 2 whole tablets 3 whole tablets Don't know Other (specify)_____	1 2 3 4 888 999	
Q3063.	Is (NAME) still taking zinc?	Yes No Don't know	1 2 888	
Q3064.	Does (NAME) still have diarrhea?	Yes No Don't know	1 2 888	
Q3065.	Did you think this zinc treatment was effective in treating (NAME)?	Yes No Don't know	1 2 888	**→3067** **→3068**
Q3066.	Why do you think it was effective?	Diarrhea stopped quickly Child recovered quickly Child regained appetite Child has not had diarrhea again Don't know Other (specify)_____	1 2 3 4 888 999	**All should skip to 3068**
Q3067.	Why don't you think it was effective?	Diarrhea did not stop soon Child didn't like the taste Too hard to administer Diarrhea started again Don't know Other (specify)_____	1 2 3 4 888 999	
Q3068.	Do you plan on using zinc the next time (NAME) has diarrhea?	Yes No Don't know	1 2 888	
Q3069.	Did you purchase the zinc or obtain it free from the	Purchased Obtained it for free	1 2	**→3070**

	health center?			
3069A	***For those that obtained it free:*** How did you obtain the free zinc?	Redeemed voucher for Kit Yamoyo Free from health center Other, (specify)_____	1 2 999	→Mod 6 →Mod 6 →Mod 6
Q3070.	What price did you pay?	Price_____ Don't know	 888	 →Mod 6
Q3071.	What do you think of the price of zinc? **Interviewer: Read options and ask respondent to select one response.**	Not expensive Affordable Expensive Too expensive No opinion Don't know	1 2 3 4 5 888	
Q3072.	If the price of zinc exceeded what you would be willing or able to pay, what would you do?	Find cheaper brand Stop using them Other (specify)_____	1 2 999	
3073.	**Interviewer: If negative responses given in Q3016 AND Q3031 AND Q3042 AND Q3050 indicating that they gave no treatments (including no ORS/SSS or home remedies), ask the following. Multiple responses allowed. Do not read list.** Can you tell me why you did not provide any treatment to (NAME) during this recent episode of diarrhea?	Child not very sick Could not afford Did not know where to get treatment Child too young for drugs Health center had no treatment Child has never had diarrhea Don't know Other (specify)_____	1 2 3 4 5 6 888 999	**All Skip to Mod 6**

Module 4: For caregivers of children under age 5 years <u>who did not</u> have a child with diarrhea within last two weeks.

4001.	When one of your children under the age of five has diarrhea, where would you most frequently seek **advice**?	Health center/clinic/hospital Community health worker Private pharmacy Neighbor/friend/family member Traditional Healer NGO/ Faith-based organization/CBO Private shop/Community Retailer/Intemba Kit Yamoyo Promoter Do not seek advice Don't know Other ,(specify)_____	1 2 3 4 5 6 7 8 9 88 99 9	
4002.	When one of your children under the age of five has diarrhea, where would you most frequently seek **treatment**?	Health center/clinic/hospital Community health worker Private pharmacy Neighbor/friend/family member Traditional Healer NGO/ Faith-based organization/CBO Private shop/Community Retailer/Intemba Kit Yamoyo Promoter Do not seek treatment Don't know Other , (specify)_____	1 2 3 4 5 6 7 8 9 88 99 9	
4003.	When one of your children under the age of five has diarrhea, what do you most often do to treat him or her? **Interviewer: do not read list. Ask respondent to state only ONE answer – the most frequently used treatment.**	<u>Give more than usual amount of fluids</u> <u>Give ORS</u> <u>Give homemade sugar salt solution (SSS)</u> <u>Give home-based fluids (not ORS or SSS)</u> <u>Give antibiotic (e.g. flagyl)</u> <u>Give antidiarrheal</u> <u>Give more than usual to eat</u> <u>Continue breastfeeding</u> <u>Take to clinic or hospital</u> <u>Use Kit Yamoyo - diarrhea treatment kit</u> <u>Don't typically do anything</u> <u>Don't know</u> <u>Other (specify)</u>_____	1 2 3 5 6 7 8 9 10 11 12 88 99	

			9	
4004.	Probe: In addition to the answer just provided, what else (if anything) do you do most often to treat him or her? **Interviewer: do not read list. Ask respondent to choose only ONE answer – the second most frequently used treatment.**	Give more than usual amount of fluids Give ORS Give SSS Give home-based fluids(not ORS or SSS) Give antibiotic Give antidiarrheal Give more than usual to eat Continue breastfeeding Take to clinic or hospital Use Kit Yamoyo - diarrhea treatment kit Don't typically do anything Don't know Other (specify)_____	1 2 3 4 5 6 7 8 9 10 11 12 88 8 99 9	
4005.	When one of your children under 5 has diarrhea, do you give less than usual to drink, about the same amount, more than usual to drink, or nothing to drink? ***(Interviewer: If "less," probe: would you give much less than usual to drink or somewhat less?)***	Much less Somewhat less About the same More Nothing to drink Don't know	1 2 3 4 5 88 8	
4006.	When one of your children under 5 has diarrhea, do you normally continue to breastfeed during the episode? **(*Interviewer: Probe: More or Less?)***	**YES** Breastfed more Breastfed less Breastfed about the same **No** Neverbreastfed Stopped breastfeeding due to diarrhea Does not breastfeed anymore/weaned/too old Other (Specify) Don't know	 1 2 3 4 5 6 99 9 88 8	
4007.	When one of your children under 5 has diarrhea, do you normally give less than usual to **eat,** about the	Much less Somewhat less About the same More	1 2 3 4	

	same amount, more than usual, or nothing? **Interviewer: If "less," probe: much less than usual to eat or somewhat less?**	Nothing to eat Don't know	5 88 8	
Q4008.	Thinking back over the past 3 months, have you seen or heard any messages about treatment for diarrhea?	Yes No	1 2	 →4012
Q4009.	Where did you hear/see the message(s) about treatment for diarrhea? **Interviewer: Multiple responses allowed. Note all that apply. Do not read list.**	Radio Television Community education session/health talk Community health worker Health clinic nurse/doctor/clinical officer Neighbor/friend Newspaper School Church Banner/poster/etc Private shop/Community Retailer/Intemba Kit Yamoyo Promoters Other specify)_____	1 2 3 4 5 6 7 8 9 10 11 12 99 9	→4012 →4012 →4010 →4010 →4010 →4010 →4012 →4010 →4010 →4011 →4010 →4010 →4012
Q4010.	Was the person delivering the message wearing a t-shirt that looked like this? SHOW PICTURE OF ORANGE PROMOTERS T-Shirt and RED Shop Keeper Shirt (Include on tablet if possible)	YES NO Don't remember	1 2 3	→4012 →4012 →4012
Q4011.	Was it one of these posters? Show Picture of Kit Yamoyo promotional posters (include on tablet if possible)	YES NO Don't remember	1 2 3	
Q4012.	Do you know what ORS is?	Yes	1	

	(**Interviewer: refer to it in different ways – local name (Manziyamoyo), Oral Rehydration Salts, and *show image of local ORS packets on screen noting that they sometimes look like this.***	No	2	**→4029**
Q4013.	In the past 3 months have you heard any messages about ORS?	Yes No	1 2	**-> 4014** **->4015**
Q4014.	Where did you hear/see the message(s) about ORS? **Interviewer: Multiple responses allowed. Note all that apply. Do not read list.**	Radio Television Community education session/health talk Community health worker Health clinic nurse/doctor/clinical officer Neighbor/friend Newspaper School Church Banner/poster/etc Private shop/Community Retailer/Intemba Kit Yamoyo Promoters Other specify)_____	1 2 3 4 5 6 7 8 9 10 11 12 99 9	→4015 →4015 →4014a →4014a →4014a →4014a →4015 →4014a →4014a →4014b →4014a →4014a →4015
Q4014A	Was the person delivering the message wearing a t-shirt that looked like this? **SHOW PICTURE OF ORANGE PROMOTERS T-Shirt and Red Retailer Shirt (Include on tablet if possible)**	YES NO Don't remember	1 2 3	**→4015** **→4015** **→4015**
Q4014B	Was it one of these posters? **Show Picture of Kit Yamoyo promotional**	YES NO Don't remember	1 2 3	

	posters (include on tablet if possible)			
Q4015.	Please tell me if you agree or disagree with each of these statements. **Interviewer: Read this list.**	Ag Dis DK ORS is medicine that gives good health 1 2 888 ORS is a treatment for diarrhea 1 2 888 ORS stops Diarrhea 1 2 888 My child does not like the taste of ORS 1 2 888 ORS prevents Dehydration 1 2 888		
Q4016.	Can you describe the process of how to make ORS Solution in as detailed a way as possible? ***(multiple answers allowed. check all that are mentioned by caregiver. Do not read responses. Only check boxes that are mentioned by respondent)***	Mix contents of ORS package with water Ensure water is clean/Purify water Ensure proper measurement of water Wash hands prior to preparing Respondent explains how to use Kit Yamoyo Sprinkle over food Swallow Powder Don't know Other (specify)_____	1 2 3 4 5 6 7 88 8 99 9	
Q4017.	Do you think ORS treatment is effective in treating diarrhea?	Yes No Don't know	1 2 88 8	**→4019** **→4020**
Q4018.	Why do you think ORS is	Diarrhea stops quickly	1	**→4020**

	effective? ***(Do not read responses. Multiple responses allowed. Only check boxes that are mentioned by respondent)***	Child recovers quickly Child regains appetite Prevents dehydration Don't know Other (specify)_____	2 3 4 88 8 99 9	**→4020** **→4020** **→4020** **→4020** **→4020**
Q4019.	Why don't you think ORS is effective in treating diarrhea? ***(Do not read responses. Multiple responses allowed. Only check boxes that are mentioned by respondent)***	It only prevents dehydration It is only for giving strength Diarrhea does not stop soon/diarrhea continues Child doesn't like the taste Too hard to administer Don't know Other (specify)_____	1 2 3 4 6 88 8 99 9	
Q4020.	Do you plan on using ORS the next time your under 5 child has diarrhea?	Yes No Don't know	1 2 88 8	
Q4020A	Thinking back over the past 6 months, have you heard a message/received information about an anti-diarrheal kit called Kit Yamoyo? **Interviewer: Show Image of Kit Yamoyo *and an actual Kit Yamoyo***	YES NO Don't Know	1 2 88 8	
Q4020B	Have you ever used the Kit Yamoyo to treat any of your children under-5 with diarrhea?	YES NO Don't know	1 2 88 8	**→Mod 7** **→4021**
Q4020C	If no, why did you not use the Kit Yamoyo to treat your child's diarrhea? **Multiple responses**	Child has not had diarrhea Kit is too expensive Kit was not available at my local shop I prefer to go to the health center	1 2 3 4	

	allowed. Do not read list.	I have not heard about it/Do not know what it is Don't Know Other, Specify_____	5 88 8 99 9	
Q4021.	Have you ever prepared ORS solution for your under 5 child?	Yes No	1 2	**→Q4025**
Q4021a	Which ORS product(s) was given to your under 5 child? ***(Interviewer: Multiple responses allowed. If they don't know you can show them the poster with samples of local products (ORS packets), and the actual Kit Yamoyo, and ask respondent to select any/all used during the recent episode of diarrhea.)*** ***If more then one answer is selected, confirm that they used two different types of ORS during the most recent episode of diarrhea***	GRZ (Health Center) From Kit Yamoyo Other from Private shop (eg. Novalyte)? Don't know	**1** **2** **3** **88** **8**	**→Mod7**
4022.	Do you use ordinary water or do you use treated water when you prepare ORS?	Ordinary (Non-purified) Water Treated Water (chlorine) Treated Water (Boiled) Other (specify)_____	1 2 3 99 9	
4023.	How much of the ORS packet/sachet would you typically use each time you prepare the ORS solution? **Interviewer: If they don't know how to respond, you may give examples**	Entire contents of packet Half off the packet Less than half of the packet Other, Specify_____	1 2 3 99 9	

	from the list			
4024.	What quantity of water would you mix the ORS with each time you prepare the solution? **Interviewer: If they don't know the particular metric measurement, probe as to what type of container they would use to measure the amount of water. Do not read list of responses.** **(Show images of each)**	Used1 standard household drinking cup/mug/glass Used Kit Yamoyo Container Used a large bottle of cola/soda (full) 200Milliliters 750 Milliliter 1 Liter 2 Liters 2.5 liter container (full) Don't Know Other Specify_____	1 2 3 4 5 6 7 8 88 8 99 9	
4025.	From where would you typically obtain ORS?	Health center/clinic/hospital Community health worker Private pharmacy Neighbor/friend, family member Traditional Healer Private shop/Retailer/Intemba Don't know Other (specify)_____	**1** **2** **3** **4** **5** **6** **88** **8** **99** **9**	**→Q4027** **→Q4027** **→Q4027** **→Q4027** **→Q4027** **→Q4027** **→Q4027**
4026.	From which health facility would you obtain the ORS?	[_____ ___]		
Q4026 A	How much would you spend on transport to get to the health center, if anything? **If they spent nothing to get there, put "0"**	[_____]Kwacha Don't know		
Q4026 B	How much would you typically spend on food and drinks during your trip to the health center, if any? **If they spent nothing, put "0"**	[_____]Kwacha Don't know	 **88** **8**	
Q4026	What other expenses if any,	Medicines	**1**	

C	would you typically have during your trip to the health center?	User fee at clinic None Other, Specify_____	**2** **3** **99** **9**	**→4027**
Q4026D	How much would you typically spend on this?	[_____] don't know	 88 8	
4027.	How far is the location you would typically obtain ORS from? **(Interviewer: Ask for answer in Km)**	[_____] km Don't know	 88 8	
4028.	How long would it take to walk there? **Interviewer: If they say they do not walk, ask them how long it would take to walk there**	Minutes (_____) 1 hour = 60 mins 2 hours = 120 mins 3 hours = 180 mins 4 hours = 240 minutes		
4029.	When your under 5 child has had diarrhea in the past, have you ever given them home-prepared sugar-salt solution (SSS)? **Insert above the local term(s) for the sugar-salt solution (as distinguished from purchased ORS – explain 1 teaspoon of salt to 6 teaspoons of sugar in a liter of water)**	Yes No Don't know	1 2 88 8	 **→Q4032** **→Q4032**
4030.	Interviewer: check responses to Q4021 and Q4029 If Q4021=2 (NO) AND Q4029=2 (NO) then go to Q4031. Otherwise, go to Q4032.			
4031.	***Interviewer: If the caregiver does not provide either ORS or SSS to the child, ask*** "why	Child not seriously ill Normally cannot find ORS/SSS to buy Products too costly	1 2 3 4 5	

	have you never given your under 5 child either ORS or home-prepared sugar-salt solution to treat diarrhea?" ***[Interviewer: Do not read list. Multiple responses allowed.]***	Child/Mother does not like Didn't know about ORS/SSS Health centerusually does not have any No nurse/doctor/health staff available at clinic Give other medicine Don't know how to make SSS Forgot about ORS/SSS Other (specify)_____	6 7 8 9 10 999	
4032.	When one of your children under 5 child has diarrhea do you ever give anything other than ORS or home-prepared treatment to treat the diarrhea?	Yes No Don't know	1 2 888	→4034 →4034
4033.	Can you tell me or show me what treatments you would give to your under 5 child if he/she had diarrhea? **Multiple responses allowed**	Kit Yamoyo Zinc other than from Kit Yamoyo ORS other than from Kit Yamoyo Antibiotic (e.g. flagyl) Anti-diarrheal Anti-malarial Other pill/syrup Intravenous fluid Vitamins Herbal/traditional remedy Don't know Other (specify)_____	1 2 3 4 5 6 7 8 9 10 888 999	
4034.	Have you ever heard about zinc as a treatment for childhood diarrhea? **Show respondent pictures of Zinc examples to verify**	Yes No Don't know	1 2 888	**→Q4058** **→ Q4058**
4035.	Can you tell me what you know about zinc? **Interviewer: Multiple responses allowed. Do**	Zinc is appropriate medicines for diarrhea Makes child stronger Zinc reduces the duration of the diarrheal episode	1 2 3	

	not read list. **Probe: anything else?**	Zinc reduces the severity of diarrhea The risk of new episode in the future is reduced Zinc is available in health centers Zinc should be taken with ORS/ORT A complete 10-day course should be administered Zinc is a micronutrient Zinc is used for malnutrition Don't know Other (specify)_____	4 5 6 7 8 9 10 888 999	
4036.	Thinking back over the last **3 months**, have you heard any messages or received information about zinc?	Yes No Don't know	1 2 888	 **->4041** **->4041**
4037.	Where did you hear/see the message(s) about zinc? **Interviewer: Multiple responses allowed. Note all that apply. Do not read list.**	Radio Television Community education session/health talk Community health worker Health clinic nurse/doctor/clinical officer Neighbor/friend Newspaper School Church Banner/poster/etc Private shop/Community Retailer/Intemba Kit Yamoyo Promoters Other specify)_____	1 2 3 4 5 6 7 8 9 10 11 12 999	→4040 →4040 →4038 →4038 →4038 →4038 →4040 →4038 →4038 →4038 →4038 →4040 →4040
Q4038.	Was the person delivering the message wearing a t-shirt that looked like this? **SHOW PICTURE OF ORANGE PROMOTERS T-Shirt and Red Retailer Shirt (Include on tablet if possible)**	YES NO Don't remember	1 2 3	**→4040** **→4040** **→4040**

4039.	Was it one of these posters? **Show Picture of Kit Yamoyo promotional posters (include on tablet if possible)**	YES NO Don't remember	1 2 3	
4040.	What information did you get from the message(s) that you heard? **Interviewer: Multiple responses allowed.** **Probe: anything else?**	Zinc reduces the duration of the diarrheal episode Zinc reduces the severity of diarrhea The risk of new episode in the future is reduced Zinc is available in health centers Zinc should be taken with ORS/ORT A complete 10-14 day dose should be administered Zinc is an appropriate treatment for diarrhea Zinc is a micronutrient Zinc is used for malnutrition Don't know Other (specify)_____	1 2 3 4 5 6 7 8 9 888 999	
4041.	Has anyone ever recommended use of zinc to treat diarrhea?	Yes No Don't know	1 2 888	→Q4043 →Q4043
4042.	If yes, who recommended zinc? ***(Interviewer: Do not read list. Multiple responses allowed.).***	Health center/clinic/hospital Community health worker Private pharmacy Neighbor/friend/family member Traditional Healer NGO/ Faith-based organization/CBO Private shop/Community Retailer/Intemba Kit Yamoyo Promoter Don't know Other , (specify)_____	1 2 3 4 5 6 7 8 888 999	
4043.	Have you ever used zinc to treat [NAME] with diarrhea?	Yes No Don't know	1 2 888	**→4045** **→Mod6**
4044.	If NO, can you tell me why you have not given your	Never heard of zinc Did not know where to buy Zinc is too expensive	1 2 3	**From here**

	child zinc to treat the diarrhea?	Used another product I had confidence in Don't think it works I had it, but didn't know I was supposed to use it Other (specify)_____	4 5 6 999	**skip to Q4058**
4045.	Which type of zinc product did you use?	Tablets from health center Tablets from Kit Yamoyo Syrup Don't know Other, specify_____	1 2 3 888 999	→4046 →4046 →4046
Q4045 a	How many zinc tablets did you receive?	(_____) Don't know	888	
Q4045 b	How many zinc tablets did you give [NAME] per day?	_____ Don't Know	888	
Q4045c	How many days did you give zinc to (NAME)?	_____ Don't Know	**888**	If greater than 9, go to 4046
Q4045 d	**Interviewer: If less than 10 tablets ask:** Was there a reason (NAME) took less than 10 tablets? **Interviewer: Do not read list. Multiple responses allowed.**	Child was cured Child would not take zinc treatment Child vomited treatment Needed treatment for another person Wanted to save remaining treatment for future illness Did not know child needed to take entire treatment Thought I needed to give zinc only along with ORS Child still taking the treatment Other (specify)_____	1 2 3 4 5 7 8 9 999	
4046.	If your child had diarrhea, can you tell me all the places you could get zinc? **Interviewer: Multiple responses allowed. Do not read responses.** **Probe: anywhere else?**	Health center/clinic/hospital Community health worker Private pharmacy Neighbor/friend, family member Traditional Healer Private shop/Intemba Don't know	**1** **2** **3** **4** **5** **6** **888**	

		Other (specify)_____	**999**	
4047.	What is the main reason you would choose these sources of supply? **Interviewer; Mark only one answer. Do not read list.**	Price Easily accessible Quality of care Most knowledgeable source Other (Specify)_____	1 2 3 4 999	
4048.	When your child under 5 has diarrhea, would you give ORS or SSS along with zinc?	Yes No	1 2	→Q4050
4049.	What is the primary reason you would not give ORS or SSS along with zinc? **Interviewer: Do not read list. Mark only one response.**	Did not know it should be given together Did not have ORS Don't think ORS is effective Didn't have ingredients for ORT too expensive Other (specify)_____	1 2 3 4 5 999	
Q4050.	Do you think zinc treatment is effective in treating diarrhea?	Yes No Don't know	1 2 888	**→4051** **→4052** **→4053**
4051.	Why do you think zinc is effective for treating diarrhea? ***(Do not read responses. Multiple responses allowed. Only check boxes that are mentioned by respondent)***	Diarrhea stopped quickly Child recovered quickly Child regained appetite Child has not had diarrhea again Don't know Other (specify)_____	1 2 3 4 888 999	
4052.	Why don't you think zinc is effective in treating diarrhea? ***(Do not read responses. Multiple responses allowed. Only check boxes***	Diarrhea did not stop soon Child didn't like the taste Too hard to administer Diarrhea started again Don't know Other (specify)_____	1 2 3 4 888 999	

	that are mentioned by respondent)			
4053.	Do you plan on using zinc the next time your under 5 child has diarrhea?	Yes No Don't know	1 2 888	
4054.	When you used zinc, did you purchase the zinc or obtain it free from the health center?	Purchased Free	1 2	→Mod6
4055.	What price did you pay?	Price_____ Don't know	 888	
4056.	What do you think of the price of zinc? **Interviewer: Read options and ask respondent to select one response.**	Not expensive Affordable Expensive Too expensive No opinion Don't know	1 2 3 4 5 888	
4057.	If the price of zinc exceeded what you were willing or able to pay, what would you do?	Find cheaper brand Stop using them Other (specify)_____	1 2 999	
4058.	**Interviewer: If negative responses given in Q4021 AND Q4029 AND Q4034 AND Q4044 indicating that they have never given any treatments (including no ORS/SSS or home remedies), ask the following. Multiple responses allowed. Do not read list.** Can you tell me why you have never provided any	Child not very sick Could not afford Did not know where to get treatment Child too young for drugs Health center had no treatment Child has never had diarrhea Don't know Other,(specify)_____	1 2 3 4 5 6 888 999	**All Skip to Mod 6**

	treatment to (NAME) during an episode of diarrhea?			

I would now like to ask you some questions about hand-washing
Module 6: Hand-washing (Everyone)

Q6001.	Do members of your household typically wash their hands with soap before eating a meal?	Yes, sometimes Yes, always Not at all	1 2 3	
Q6002.	Please show me where members of your household most often wash their hands	Observed Not Observed Not in dwelling/plot/yard No permission to see Other Reason	1 2 3 4 999	**→6005** **→6005** **→6005** **→6005**
Q6003.	Observe Presence of Water at the specific place for hand-washing. **Verify by checking the tap/pump, or basin. Bucket, water container or similar objects for presence of water.**	Water is available Water is not available	1 2	
Q6004.	Record if soap or detergent is present at the specific place for hand-washing. **Circle all that apply** **Include image of Kit Yamoyo bar of soap so interviewer can identify**	Other Bar Soap Detergent (Powder/Liquid/Paste) Liquid Soap Ash/Mud/Sand Kit Yamoyo bar of soap None Other, Specify_____	1 2 3 4 5 6 999	→Mod5 →Mod5 →Mod5 →Mod5 →Mod5 →6005
Q6005.	Do you have any soap or detergent (or other locally used cleansing agent) in	Yes No	1 2	 →Mod

	your household for washing hands?			5
Q6006.	Can you please show it to me? Record observation. Circle all that apply.	Bar Soap Detergent (Powder/Liquid/Paste) Liquid Soap Ash/Mud/Sand Kit Yamoyo Bar of Soap None No permission to see Other Reason	1 2 3 4 5 6 7 999	

Module 7:
We would now like to ask you some questions about the Kit Yamoyo and your experience with it.

Number	Questions	Responses	Number	Skip to
Q7000X **This question is to confirm use of Kit Yamoyo**	Did (Name) use the Kit Yamoyo anti-diarrhea Kit when he or she had diarrhea last?	Yes No Don't Know	1 2 888	**→3017** **→3017**
Q7000X1	When you used the Kit Yamoyo, was it: Newly acquired and unopened Newly acquired but open Previously acquired but unopened; OR Previously acquired and previously used some of the contents	Newly acquired and unopened Newly acquired but open Previously acquired but unopened Previously acquired and previously used some of the contents Other, Specify_____	1 2 3 4 999	
Q7000	Have you yourself, or any other people in your household over the age of 5	Yes No Don't know	1 2 888	

	ever used the Kit Yamoyo?			
Q7001.	Have you ever attended an education/promotion event for the Kit Yamoyo?	Yes No Don't know	1 2 888	→7002a →7002a
Q7002.	If no, where did you see/hear about the Kit Yamoyo? **<u>Multiple responses allowed. Do not read list.</u>**	Radio Television Community education session/health talk Community health worker Health clinic nurse/doctor/clinical officer Neighbor/friend Newspaper School Church Banner/poster/etc Private shop/Community Retailer/Intemba Kit Yamoyo Promoters Other specify)_____	1 2 3 4 5 6 7 8 9 10 11 12 999	**For all responses skip to Q7003**
<u>Q7002a</u>	Did the promotion event have an influence on your decision to obtain a Kit Yamoyo?	Yes No Don't Know	1 2 888	
Q7003.	What are the key messages you have received with regard to Kit Yamoyo? **Interviewer: Mark all that are mentioned. Do not read list.** **Probe: Any**	Use ORS & Zinc together to treat diarrhea Can buy Kit Yamoyo at the local shop Mix 1 sachet with Kit Yamoyo container full of water Give 1 tablet of zinc per day Finish all ten pills of zinc Give ORS after each liquid stool/loose motion Wash hands with soap Give antibiotic (e.g. Flagyl) Give more than usual amount of fluid	1 2 3 4 5 6 7 8 9	

	messages at all?	Continue breastfeeding Take to clinic/health center/hospital when danger signs (i.e. blood in stool, severely dehydrated, vomiting) Other, Specify_____	10 11 999	
Q7004.	How many Kit Yamoyo's have you ever obtained?	_____ Don't Know	 **888**	
Q7005.	From where did you obtain your most recent Kit Yamoyo?	Private shop/Community Retailer/Intemba Health center/clinic/hospital Community health worker Neighbor/friend/family member Traditional Healer NGO/ Faith-based organization/CBO Don't know Other (specify)_____	 **1** **2** **3** **4** **5** **6** **888** **999**	 **→7007** **→7006** **→7010** **→7010** **→7010** **→7010** **→7010** **→7010**
Q7006.	From which health facility did you obtain the Kit Yamoyo?	[_____]		**→7010**
Q7007.	From which retailer did you obtain the Kit Yamoyo? **Interviewer: Name of shop or shop owner is what should be recorded**	[_____]		
Q7007a	Did you find the retailer to be helpful with regard to the	Yes No Don't know	**1** **2** **888**	

	Kit Yamoyo?			
Q7008.	Did the retailer/shop owner give any advice, instructions, or guidance when you got the Kit Yamoyo?	Yes No Don't know	**1** **2** **888**	 **→7010** **→7010**
Q7009.	What advice, instructions, or guidance did the retailer provide? **Interviewer: Mark all that are mentioned. Do not read list.** **Probe: Any guidance at all?**	Use ORS & Zinc together to treat diarrhea Can buy Kit Yamoyo at the local shop Mix 1 sachet with Kit Yamoyo container full of water Give 1 tablet of zinc per day Finish all ten pills of zinc Give ORS after each liquid stool/loose motion Wash hands with soap Give antibiotic (e.g. Flagyl) Give more than usual amount of fluid Continue breastfeeding Take to clinic/health center/hospital when danger signs (i.e. blood in stool, severely dehydrated, vomiting) Other, Specify_____	1 2 3 4 5 6 7 8 9 10 11 999	
Q7010.	Did you pay for the Kit Yamoyo or use a voucher the last time you obtained one?	Paid Voucher Don't know	**1** **2** **888**	**→7012** **→7013**
Q7011.	How much did you pay?	(_____)		**→7013**
Q7012.	From where did you acquire the voucher?	Kit Yamoyo Promoter Health center/clinic/hospital Community health worker Neighbor/friend/family member Private shop/Community Retailer/Intemba Don't know	**1** **2** **3** **4** **5** **6** **888** **999**	

		Other (specify)_____		
Q7012a	Would you have tried the Kit Yamoyo if you did not receive a voucher?	Yes No Don't Know	1 2 888	
Q7013.	What do you think of the retail price of the Kit Yamoyo (5000 Kwacha or 5KR)? **Interviewer: Read options and ask respondent to select one response.**	Not expensive Affordable Expensive Too expensive No opinion Don't know	1 2 3 4 5 888	
Q7014.	How far from your household was the location the Kit Yamoyo was obtained from? **(Interviewer: Ask for response in Km)**	[_____] km Don't know	**888**	
Q7015.	How long did it take to walk there from your home? **Interviewer: If they say they did not walk, ask them how long it would take to walk there.**	Minutes [_____] Don't Know 1 hour = 60 mins 2 hours = 120 mins 3 hours = 180 mins 4 hours = 240 minutes	**888**	
Q7015a	Is this the closest retail shop to your home?	Yes No Don't Know	1 2 888	
Q7015b	What was your main reason for choosing	Price Easily accessible Quality of care	1 2 3	

	this source of supply? **Interviewer; Mark only one answer. Do not read list.**	Most knowledgeable source Only place I know to get it Other (Specify)	4 5 999	
Q7016.	Does a local shop always have Kit Yamoyo in stock and available? **Interviewer: you may read the response list.**	Yes, always No, never Usually Don't Know	1 2 3 888	
Q7017.	How many days after the diarrhea began did you first <u>seek out the Kit Yamoyo</u>? **Interviewer: If the same day, record '00;** **If Child did not have diarrhea when Kit Yamoyo was acquired record 222.**	**[_][_]** Child did not have diarrhea when I acquired Kit Yamoyo Don't know	 222 888	
Q7018.	How many days after the diarrhea began did your child first <u>use the Kit Yamoyo</u>? **Interviewer: if same day mark '00'** **If the Kit Yamoyo has not been used yet record 222.**	(____) Have not used it yet Don't Know	 222 888	

Q7019.	Can you name all of the items found in the Kit Yamoyo? **Interviewer: Multiple answers allowed. Click all that are mentioned. Do not read list.**	ORS Zinc Soap Instructions	1 2 3 4	
Q7020.	Did you use the instructions found in the Kit Yamoyo?	Yes No Don't Know	1 2 888	**→7024** **→7024**
Q7021.	Did you find the instructions useful?	Yes No Don't Know	1 2 888	
Q7022.	What did you like most about the instructions? **Multiple responses allowed. Mark all that are mentioned. Do not read list.** **Probe: Anything else?**	Instructions were clear Diagrams/pictures Instruction are in my language Instruction are in colour Don't Know Other, specify_____	1 2 3 4 888 999	
Q7023.	What, if anything, did you find unclear in the instructions? **Multiple responses allowed. Do not read list.** **If necessary, probe: Can you be more specific?**	Container to be used as measure for water One packet of ORS to be mixed with 1 container full of water How many packets of ORS to use How often to give ORS How many zinc tablets to give How long to give zinc for	1 2 3 4 5 6 7	

		What is the soap for Nothing was unclear Other, Specify_____	8 999	
Q7023a	Can you describe the process of how to use the Kit Yamoyo? ***(multiple answers allowed. check all that are mentioned by caregiver. Do not read responses. Only check boxes that are mentioned by respondent)***	Wash hands prior to preparing Remove seal Mix contents of 1 sachet of ORS with Kit Yamoyo container full of water Ensure water is clean/Purify water/Boil water Let boiled water cool before pouring into Kit Yamoyo container Shake Kit Yamoyo container with lid on to mix the ORS and water together Give ORS after each watery stool Take 1 tablet of zinc per day Take full course of zinc tablets until finished (10 days) Don't know Other (specify)_____	1 2 3 4 5 6 7 8 9 888 999	
Q7024.	How many packets of ORS from the Kit Yamoyo did you prepare for your child during the episode of diarrhea?	_____ Don't Know	888	

Q7025.	Did you use ordinary water or did you use treated water when you prepared the Kit Yamoyo ORS?	Ordinary (Non-purified) Water Treated Water (chlorine) Treated Water (Boiled) Other (specify)_____	1 2 3 999	
Q7026.	How much of the ORS packet/sachet did you use each time you prepared the ORS? **(*Interviewer: If they don't know how to respond, you may give examples from the list*)**	Entire contents of packet Half of the packet Less than half Other Specify_____	1 2 3 999	
Q7027.	What quantity of water did you mix the ORS with each time you prepared the solution?	Used1 standard household drinking cup/mug/glass Used Kit Yamoyo Container Used a large bottle of cola/soda (full) 200Milliliters 750 Milliliter 1 Liter 2 Liters 2.5 liter container (full) Don't Know Other Specify_____	1 2 3 4 5 6 7 8 888 999	→7029 →7029 →7029 →7029 →7029 →7029 →7029 →7029 →7029 →7029
Q7028.	Till what level did you fill the Kit Yamoyo container with water to mix the solution?	Filled to top Filled to line marked on container Filled it up half way Don't know Other, specify_____	1 2 3 888 999	
Q7029.	For how many days did you give the child the ORS from Kit Yamoyo?	**[_][_]**		

Q7030.	How often did you give the ORS solution from Kit Yamoyoto your child? ***(Interviewer: Read the list and ask respondent to select one response.)***	Frequently After each liquid stool Morning, mid-day, and night Whenever the child wanted it Don't know Other (specify)_____	1 2 3 4 888 999	
Q7031.	Did you use each of the items in the Kit Yamoyo when your child had diarrhea – the ORS, zinc, and soap?	Yes No Don't know	1 2 888	
Q7031A	Did you use the ORS?	Yes No Don't know	1 2 888	**→7032A**
Q7031B	Did you use the Zinc tablets?	Yes No Don't know	1 2 888	**→7032A**
Q7031C	Did you use the bar of soap?	Yes No Don't know	1 2 888	**→7032B** **→7032A**
Q7032.	Which items did you not use? **Multiple answers allowed. Click all that apply.**	ORS Zinc Soap	1 2 3	**→skip Q7032B if respons e3 is selected**
Q7032a	Why did you not use the item(s)?	Child did not have diarrhea Don't think it works Child did not like it Did not know how to use it Forgot to use Other, specify	1 2 3 4 5 999	**All to Q7033**
Q7032b	What did you use the soap for?	Hand-washing Clothes Washing	1 2	

	Multiple Responses Allowed	Bathing Other, Specify_____	3 999	
Q7033.	Had you ever heard about zinc as a medicine for diarrhea prior to learning about the Kit Yamoyo?	Yes No Don't know	1 2 888	
Q7034.	Was the zinc from the Kit Yamoyo the first time your child has ever had zinc as a treatment for diarrhea?	Yes No Don't Know	1 2 888	**If NO to 7031B Skip this question**
Q7035.	Can you tell me what you know about zinc? **Interviewer: Multiple responses allowed. Do not read list. Mark all responses.** **Probe: anything else?**	Zinc is appropriate medicines for diarrhea Makes child stronger Zinc reduces the duration of the diarrheal episode Zinc reduces the severity of diarrhea The risk of new episode in the future is reduced Zinc is available in health centers Zinc should be taken with ORS/ORT A complete 10-day course should be administered Zinc is a micronutrient Zinc is used for malnutrition Don't know Other (specify)_____	1 2 3 4 5 6 7 8 9 10 888 999	

Q7036.	What dose of zinc per day was given to your child? **Probe: How many tablets?**	Half tablet 1 whole tablet 2 whole tablets 3 whole tablets Don't know Other (specify)_____	1 2 3 4 888 999	**If NO to 7031B Skip this question**
Q7037.	How many days did you give zinc to your child?	_____ Don't Know	**888**	If greater than 9, go to 7039
Q7038.	**Interviewer: If less than 10 tablets ask:** Was there a reason your child took less than 10 tablets? **Interviewer: Do not read list. Multiple responses allowed.**	Child was cured Child would not take zinc treatment Child vomited treatment Needed treatment for another person Wanted to save remaining treatment for future illness Did not know child needed to take entire treatment No one told me to give all the treatment Thought I needed to give zinc only along with ORS Child still taking the treatment Other (specify)_____	1 2 3 4 5 6 7 8 999	
Q7039.	Is your child still taking zinc?	Yes No Don't know	1 2 888	**If NO to 7031B Skip this question**
Q7040.	Does your child still have diarrhea?	Yes No	1 2	
Q7041.	Did you thinkthe Kit Yamoyo was effective in treating your child's diarrhea?	Yes No Don't know	1 2 888	→7043 →7044

Q7042.	Why do you think the Kit Yamoyo was effective? ***(Do not read responses. Multiple responses allowed. Only check boxes that are mentioned by respondent)***	Diarrhea stopped quickly Child recovered quickly Child regained appetite Child has not had diarrhea again Because of the zinc Don't know Other (specify)_____	1 2 3 4 5 888 999	**→ ALL RESPONSES TO 7044**
Q7043.	Why don't you think the Kit Yamoyowas effective? ***(Do not read responses. Multiple responses allowed. Only check boxes that are mentioned by respondent)***	Diarrhea did not stop soon Child didn't like the taste Too hard to administer Diarrhea started again Don't know Other (specify)_____	1 2 3 4 888 999	
Q7044.	<u>Was it easy to find Kit Yamoyo in a place near you?</u>	Yes No Don't Know	1 2 999	
Q7045.	Did you keep the Kit Yamoyo container after you were finished with the contents?	Yes No Contents are not finished Don't know	1 2 3 888	**→7047**
Q7046.	Have you used the Kit Yamoyo container for any other purpose?	Storage of salt Storage of sugar Storage for buttons Still has contents in it Other, Specify_____	1 2 3 4 999	
Q7047.	Do you plan on using the Kit Yamoyo the next time your child has diarrhea?	Yes No Don't know	1 2 888	

Q7048.	What was the one thing you liked best about the Kit Yamoyo? **Only one response allowed. Do not read list. Looking for the top thing they liked best.**	ORS Zinc Soap Container Clear instructions Easy to access Good value/Affordable It worked/Stopped child's diarrhea ORS, Zinc and Soap together in one kit Other, specify_____	1 2 3 4 4 5 6 7 8 999	
Q7049.	What did you like least about Kit Yamoyo? **Multiple responses allowed. Do not read list.**	Had to pay for it Too expensive Not easy to find Not in stock when I needed it No antibiotic included I liked everything about it Other, Specify_____	1 2 3 4 5 6 999	
Q7050.	Do you currently have a Kit Yamoyo in your household?	Yes No	1 2	
Q7051.	Can you show it to me?	Yes, Observed No, Not Observed	1 2	
Q7052.	Is it: Newly acquired and unopened Newly acquired but open Previously acquired but unopened Previously acquired and previously used some of the contents	Newly acquired and unopened Newly acquired but open Previously acquired but unopened Previously acquired and previously used some of the contents Other, Specify_____	1 2 3 4 999	

Module 5: Awareness/likert scales. Should be answered by all respondents. (Everyone)

This section asks your opinion on certain issues.

Q5001	Children die of diarrhea mainly because of dehydration. Can you tell me some common signs of dehydration? **Interviewer: Multiple responses allowed. Do not read responses.**	Restless/irritable Sunken eyes/fontanelle Very thirsty/drinks eagerly Dark coloured urine Skin is less elastic (goes back slowly when pinched) Limp/unconscious Don't know Other specify_____	1 2 3 4 5 6 888 999	

Please tell me if you believe that the following statements are true or false. (Everyone)

Ability: Knowledge				
		True	**False**	**Don't Know**
Q5002.	Diarrhea can be associated with lack of cleanliness	**1**	**0**	**888**
Q5003.	Diarrhea can be caused by drinking unsafe water	**1**	**0**	**888**
Q5004.	Diarrhea can be caused by eating unhygienic foods	**1**	**0**	**888**
Q5005.	Only those diarrheal episodes that have blood in the stool require antibiotics	**1**	**0**	**888**
Q5006.	Most diarrhea can be managed at home without drugs	**1**	**0**	**888**

Please tell me if you agree or disagree with these statements. Probe: Read out responses (Strongly agree, agree somewhat, disagree somewhat, strongly disagree) (everyone)

	MOTIVATION: THREAT SUSCEPTIBILITY (CHILDREN UNDER 5)					
		Strongly Agree	**Agree Somewhat**	**Disagree Somewhat**	**Strongly Disagree**	**Don't Know**

Q5007.	If my child gets diarrhea it is best to do nothing and it will pass in time	**4**	**3**	**2**	**1**	**888**
Q5008.	The children (child) under 5 in my household are (is) healthy so their (his/her) bodies could fight off diarrhea without doing anything	**4**	**3**	**2**	**1**	**888**
Q5009.	Children under 5 are too young to experience serious medical problems from getting diarrhea	**4**	**3**	**2**	**1**	**888**
Q5010.	I am not worried about the children (child) under 5 in my household getting diarrhea	**4**	**3**	**2**	**1**	**888**
Q5011.	Children are more likely to get diarrhea than adults	**4**	**3**	**2**	**1**	**888**

Everyone accept those that said NO to 3008/4012 (i.e. don't know ORS) or 3042/4034 (i.e. don't know zinc). All who answered Mod 7 should answer these as well.

	Opportunity: Availability **Skip if have not heard about ORS or ZINC or DTK in Mod 3 and Mod 4**					
No.						
		Strongly Agree	**Agree Somewhat**	**Disagree Somewhat**	**Strongly Disagree**	**Don't know**
Q5012.	Shops near here always have ORS for sale	**4**	**3**	**2**	**1**	**888**
5012A	Shops near here always have Zinc for sale	**4**	**3**	**2**	**1**	**888**
Q5013.	ORS treatments are difficult to get around here	**4**	**3**	**2**	**1**	**888**
5012B	Zinc treatments are difficult to get around here	**4**	**3**	**2**	**1**	**888**

Q5014.	There is a place nearby where I can get zinc **and** ORS when my child needs it	**4**	**3**	**2**	**1**	**888**
Q5015.	I don't know where to get zinc	**4**	**3**	**2**	**1**	**888**
Q5016.	Zinc and ORS treatment products are available within walking distance from my home	**4**	**3**	**2**	**1**	**888**

GENERAL AWARENESS OF ORS: Skip only if NO to 3008 or 4012 (i.e. don't know ORS)

	Motivation: Outcome Expectations					
No.						
		Strongly Agree	**Agree Somewhat**	**Disagree Somewhat**	**Strongly Disagree**	**Don't know**
Q5017.	ORS is effective for treatment of diarrhea	**4**	**3**	**2**	**1**	**888**
Q5018.	ORS does not help prevent dehydration	**4**	**3**	**2**	**1**	**888**
Q5019.	There is no need to take a child to the health facility if there is blood in the stool	**4**	**3**	**2**	**1**	**888**
Q5020.	The amount of water mixed with the ORS does not matter	**4**	**3**	**2**	**1**	**888**
Q5021.	Children should continue eating and drinking if they have diarrhea	**4**	**3**	**2**	**1**	**888**

GENERAL AWARENESS OF ZINC: Skip only if NO to 3042 or 4034 (i.e. don't know ZINC)

	Motivation: Outcome Expectations					
No.						
		Strongly Agree	**Agree Somewhat**	**Disagree Somewhat**	**Strongly Disagree**	**Don't know**
Q5022.	Zinc is effective for treatment of diarrhea	**4**	**3**	**2**	**1**	**888**
Q5023.	Zinc reduces the duration of a diarrheal episode	**4**	**3**	**2**	**1**	**888**
Q5024.	Zinc should always be given with ORS for optimal diarrhea treatment	**4**	**3**	**2**	**1**	**888**
Q5025.	Use of zinc reduces the risk of dehydration in children	**4**	**3**	**2**	**1**	**888**

Q5026.	Zinc reduces the risk of a new diarrheal episode in the following 2 to 3 months	**4**	**3**	**2**	**1**	**888**
Q5027.	Zinc does not help in reducing the severity of a diarrheal episode	**4**	**3**	**2**	**1**	**888**
Q5028.	What is the minimum number of days that ZINC tablets should be taken? ***(Record figure in the space provided)***	[_____] days Don't Know 888				

General awareness of soap (Everyone)

Q5029.	What are the best ways to prevent germs that cause diarrhea? **Multiple Responses Allowed. Do not read list**	Purify/boil water Wash hands (with soap) Wash utensils Peel raw fruit Exclusive breastfeeding Don't Know Other, Specify_____			1 2 3 4 5 8 8 8 9 9 9	
		Strongly Agree	**Agree Somewhat**	**Disagree Somewhat**	**Strongly Disagree**	**Don't know**
Q5030.	Germs that cause diarrhea can be passed by people's hands (e.g. handshake)	**4**	**3**	**2**	**1**	**888**
Q5031.	Washing our hands with soap protects us better than with just plain water	**4**	**3**	**2**	**1**	**888**
Q5032.	Soap is too expensive so we don't use it	**4**	**3**	**2**	**1**	**888**
Q5033.	When should one wash their hands? ***INTERVIEWER: Multiple response possible. Probe for additional responses and mark all that apply)***	After using the latrine/toilet Before preparing food and drink Before eating Before feeding children After Working Don't know Other specify_____			1 2 3 4 5 888 999	

	Capacity/Ability: Use of Products **Skip if NO to 3042 or 4034 or 3017A or 4020A. Everyone from Mod 7 should answer these questions.**

No.						
		Strongly Agree	Agree Somewhat	Disagree Somewhat	Strongly Disagree	Don't know
Q5034.	Zinc is an appropriate treatment for diarrhea in children	4	3	2	1	888
Q5035.	Zinc with ORS should be used for every type of diarrhea in children	4	3	2	1	888
Q5036.	Diarrhea in children should be treated with an antibiotic	4	3	2	1	888
Q5037.	Zinc has too many side effects, so I don't feel safe giving zinc to my small child	4	3	2	1	888
Q5038.	Zinc tastes bad so my child won't take it	4	3	2	1	888
Q5039.	Zinc is only a nutritional supplement, not an effective treatment for diarrhea in children	4	3	2	1	888
Q5040.	Zinc should be given along with ORS to be most effective	4	3	2	1	888
Q5041.	It is difficult to remember to give a child zinc when the diarrhea has stopped	4	3	2	1	888
Q5042.	I would purchase and use zinc or the Kit Yamoyo the next time my child has diarrhea	4	3	2	1	888

Interviewer:
Is there anything I did not ask that you think I should know? Is there anything you want to go back to? Is there anything you would like to ask me about the topics we have discussed today?
ENUMERATORS, PLEASE ENTER ANY ADDITIONAL NOTES, ADDITIONAL OBSERVATIONS, PROBLEMS, ETC. IN THIS SECTION AS WELL.
General Responses:

Q 5044. Acquire GPS Location _____ _____

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EDUCATION

Johns Hopkins Bloomberg School of Public Health — *Baltimore, MD*
Doctor of Public Health (DrPH) — *Aug 2010 – December 2015*
Department of International Health; Health Systems

Boston University School of Public Health — *Boston, MA*
Master Of Public Health (MPH) — *Sept 2004- Jan 2006*
- International Health & Epidemiology
- Dean's Honor List; 3.99 GPA

University of Waterloo — Waterloo, ON
Honors Bachelor of Science (B.Sc.) — *Sept 2000 – Apr 2004*
- Honors Health Studies & Gerontology, Faculty of Applied Health Sciences
- National Laureate of the Canada Millennium Excellence Scholarship
- Young Alumni Award, October 2009

WORK EXPERIENCE

Antara Global Health Advisors — Toronto, Ontario/Global
Founder and CEO — *May 2012 – Present*

- Providing consulting services and technical expertise to organizations (NGOs, Governments, donors, foundations, innovators, private sector, universities, etc.) in global health and development, including services in: M&E; research design, implementation and analysis; health markets; global health delivery and implementation sciences; multi-sectoral partnership development (e.g. public-private partnerships); program management and development; innovation for development & human-centered design; global health strategy; proposal development & assessment; child health; etc.
- Advising on a strategy to improve prevention of HIV in adolescent girls in sub-Saharan Africa; **Client:** Janssen/Johnson & Johnson
- Developing multi-sectoral partnership and funding strategy to improve health of garment factory workers in Southeast Asia; **Client:** Janssen/Johnson & Johnson
- Selected as Senior Health Evaluation Specialist for Aga Khan Foundation's multi-country Central Asia Health Systems Strengthening Project mid-term evaluation; **Client:** Aga Khan Foundation Canada/DFATD
- Leading evaluation of the national scale-up of the globally recognized ColaLife model (across rural and urban, public and private sector markets); **Client:** ColaLife/CARE.
- Conducted large-scale global interview process with leaders in international health to evaluate emerging opportunities in health markets; **Client:** Rockefeller Foundation and Future Health Systems Consortium.
- Providing advice as member of an expert panel on the development of a blue print for a Backpack PLUS for Community Health Workers; **Client:** MDG Health Alliance and UNICEF
- Member of the UN Innovation Working Group under the Every Woman, Every Child Initiative; **Client:** UN
- Developing report on rural, private sector retailers and health market opportunities in emerging economies; **Client:** GlaxoSmithKline/Barclay's Partnership

University of Waterloo School of Public Health Waterloo, Ontario
Adjunct Lecturer *Dec 2012 – Present*

- Delivering guest lectures and keynotes at special events on topics relating to global health and development, social innovation, health markets and child health; representing SPHHS at external global health forums

ColaLife Canada/United Kingdom/Zambia
Public Health Advisor & Principal Investigator *Jul 2010 – Present*

- Established globally renowned, innovative, social enterprise movement as one of three executive members
- Developed an innovative public-private-partnership model in order to test to what extent leveraging the Coca-Cola supply-chain will improve access and utilization of oral rehydration salts and zinc in rural areas of developing countries
- Providing leadership and technical services relating to trial design, monitoring and evaluation, training, product innovation, partnership development, data analysis, donor reporting, fundraising and advocacy
- Worked, and gathered both quantitative and qualitative evaluation data, across diverse groups of stakeholders at multiple levels (national, provincial, district, community), including via in-depth interviews, focus group discussions, household surveys, retailer surveys, health center impact assessments, direct observation, project management meetings, documentation/records review and other methodologies
- Scaling up successful model nationally in partnership with the Ministry of Health, International NGOs, local NGOs and private sector partners.

- **Canadian International Development Agency (CIDA), Strategic Policy and Performance Branch**
- Ottawa, Ontario / Global
- Apr 2010 – Aug 2010
- *Senior Policy Analyst/Special Advisor – G8 Maternal and Child Health Initiative*

- Provided key insights and public health advise relating to Canada's **G8 Maternal and Child Health Initiative** (a.k.a. Muskoka Initiative).
- Led CIDA's involvement on the UN Secretary General's Joint Action Plan for Women's and Children's Health Working Groups on Innovation and Finance as a CIDA health expert.
- Developed white paper on Innovations in Service Delivery as part of the Joint Action Plan – posted on The Partnership for Maternal, Newborn, and Child Health's website.

Canadian International Development Agency (CIDA), Multilateral and Global Programs Branch, Global Initiatives Directorate (GID) Ottawa, Ontario / Global
Dec 2007- Apr 2010
Senior Health Advisor

- Developed Treasury Board Submission and co-developed innovative financing concept for a multilateral tuberculosis program (**TB REACH Facility)** that resulted in Government of Canada commitment of $120M in new funding for tuberculosis detection and control; **Partner:** Stop TB Partnership

- Managed and led Canadian participation on the **Affordable Medicines Facility – malaria (AMFm)**; represented Global Fund constituency of Canada, Germany and Switzerland; advocated for reaching the poor in high-level inter-governmental negotiations with numerous multilateral agencies, foundations, academics, governments and NGOs; resulted in increased emphasis and focus on reaching the poor and ensuring equity issues were incorporated into the fabric of the technical design for the pilot phase of this multi-million dollar, global initiative; **Partner:** Global Fund for AIDS, TB and Malaria
- Represented CIDA interests on the Government of Canada's **Global Health Research Initiative (GHRI) Steering Committee**; helped develop strategic directions for this global health research funding partnership; represented GHRI in G8 discussions relating to global health research collaboration; **Partner:** GHRI
- Provided evidence-based advice to senior management relating to global health funding decisions; managed multilateral tuberculosis and other health programs in order to maximize program effectiveness and efficiency; oversight and management of large-scale multilateral evaluations; analyzed program results and lessons learned for application to future policy and programming; worked with partners to ensure collaboration and harmonization.

Accenture Inc., Healthcare and Life Sciences Practice Canada

Management Consultant *Jan 2006 - Nov 2007*

- Developed core strategic and technical management consulting skills including change management, performance/program evaluation, requirements gathering, business process design, project management, staff supervision and proposal development.
- Provided industry specific strategic advice and support to senior management teams from a diverse range of health-related organizations.
- Evaluated, measured and analyzed public sector value and productivity within the Ontario Health System and coordinated a policy development process for a Director-level working group; **Client:** Ontario Ministry of Health.
- Worked with large hospital network to help develop provincial strategy for reducing wait times in 5 key surgical areas; **Client:** University Health Network
- Managed project financials, key deliverables, and vendor relations for a large scale Provincial Laboratory Information System that allows for e-sharing of laboratory results throughout Ontario; **Client:** Ontario Ministry of Health
- Conducted project management activities for Enterprise Resource Planning (ERP) implementation at large global pharmaceutical company; **Client:** Pfizer
- Played key leadership role in RFP response processes resulting in contracts ranging from $750K - $9Million.

LV Prasad Eye Institute / World Health Organization (WHO) Hyderabad, India

Project Manager / Intern *Jun-Aug 2004*

- Managed a team of three while on WHO internship through the LV Prasad Eye Institute's International Center for the Advancement of Rural Eye Care.
- Gained a deep understanding of and helped execute community eye screening programs to improve access to healthcare for under-serviced populations in remote rural villages and urban slums.
- Shadowed hospital administration and clinical staff at rural eye hospital; recommended potential improvements and cost-saving mechanisms.
- Developed study/thesis on global health delivery in developing countries based on analysis of Institute's delivery model.

Government of Canada, Health Canada, International Affairs Ottawa, ON
Directorate, International Health Policy and Communications Division *May-Aug 2003*
Jr. Policy Analyst

- Conducted literature reviews and created analytical reports to educate Canadian policy makers about innovative health practices in other countries; contributed international perspectives for analysis and development of new health policies and practices.
- Prepared report for Pakistani Minister of Health on Canadian health insurance system to aid Pakistan with health insurance plan development.
- Consulted with representatives from various Health Canada branches to develop report that streamlined all international initiatives, improving access to information and potential for collaboration.

University Health Network, Toronto Western Toronto, ON
Hospital, Department of Ophthalmology *May-Sept 2001-2002*
Vision Science Researcher

- Gained valuable analytical research and lab skills while assisting in the investigation of *the Role of Lamina Cribrosa Biomechanics and Ischemia in Glaucomatous Optic Neuropathy*.
- Simulated glaucoma in post-mortem human eye to determine and record the first physiological changes that take place within the eye using retinal tomography.
- Initiated a clinical research database system for glaucoma unit of largest Department of Ophthalmology in Canada; recognized for improving efficiency via creation of basic electronic medical records system.

VOLUNTEER EXPERIENCE

Jane Goodall Institute of Canada Canada/Africa
Board of Directors *March 2015-Ongoing*

- Providing strategic oversight and development of JGI Canada to maximize impact in the area of human/community development as well as environmental and chimpanzee conservation.
- Elected to jointly govern this international NGO through the establishment of broad policies and objectives; support and review performance of the Chief Executive Officer; help ensure availability of adequate resources; approve annual budgets; provide guidance on staffing and human resources; represent the organization to stakeholders

Unite For Sight Canada/Global
Regional Director of Canada *May 2005-Jan 2008*

- Appointed to the Unite for Sight executive team to improve and expand operations in Canada.
- Managed all Canadian operations, human and financial resources for this international 501(C)(3) non-profit organization focused on improving eye health and preventing blindness.
- Significantly increased Canadian volunteer participation; developed new Canadian chapters; attracted significant media attention; implemented Canadian arm of Ghana-based micro-credit program; developed sunglasses donations program.

UW International Health Development Association (UWIHDA) Waterloo, ON
Founder, Past Executive Director, and External Advisor *Sept 2002 – 2011*

- Created university-based non-governmental organization to raise Canadian awareness of international health disparities and development issues.
- Designed and implemented diverse international public health and development projects providing students with an annual opportunity to volunteer in a developing area.
- Managed human and financial resources, established partnerships with leading international organizations, raised substantial programming funds, and led the development of this organization to become a leading student-run non-profit.

Youth Challenge International Guyana, South America
Community Health Educator *July – Aug 2002*

- Developed and led health promotion workshops while living in three interior Amerindian communities focusing on issues including: malaria, HIV/AIDS, waterborne diseases, and nutrition.
- Helped establish first community health center in village of Malali.
- Assisted with study that introduced innovative, low-cost, bacterial replication technology utilized to reduce malaria vector populations; introduced insecticide treated bed-net programs.

QUALIFICATIONS & SKILLS

- Languages – English (fluent), French (competent), and Hindi (competent).
- Overseas experience working with international organizations in global health; substantive experience and skills in program and project management, research & evaluation; excellent organizational, oral, and written communication skills; Strong analytical and presentation skills; ability to establish working relationships with diverse groups; demonstrated reliability, judgment, and initiative; proven leadership excellence and management skills; tri-sector experience
- On-the-ground experience working in Africa, Asia, South America, North America and Europe
- Strong background in public health, health services delivery/implementation science, health markets, program development and evaluation, epidemiology, infectious and chronic diseases, health policy, tuberculosis, maternal and child health, childhood diarrhea, malaria and vision/ocular sciences.
- Substantial experience managing small and large teams of people
- Computer Skills – Microsoft Professional/Office Suite, SharePoint administration, e-mail systems, blogs, social media, web 2.0 applications, Open Data Kit + Commcare, EpiInfo, Lives Saved Tool (LiST), STATA

SELECTED AWARDS AND HONOURS

- INDEX Award 2015: Design to Improve Life, Finalist (top 4%), June 2015
- GlaxoSmithKline (GSK) – Save the Children **Healthcare Innovation Award** ("Oscars of Healthcare Innovation"), February 2015
- Financial Times/International Finance Corporation **Transformational Business Award** – Health Category, May 2014
- Highlighted as a "Best Buy in Global Health". Impact Magazine. Retrieved from http://www.redorbit.com/news/health/1112958787/innovations-save-lives-of-mothers-and-children/
- Highlighted at the **UN General Assembly** for selection as one of 10 Breakthrough Innovations in Child Health (for the Kit Yamoyo anti-diarrhea kit) – PATH and the Every Woman, Every Child Initiative, September 2013

- Obeserver (UK Newspaper) **Ethical Product of the Year Award** (for the Kit Yamoyo anti-diarrhea kit), June 2013
- Winner of the Diamond Award (Top Award) and the **Food Security Award** at the 25th Dupont Packaging Innovation Awards (for the Kit Yamoyo anti-diarrhea kit), May 2013
- International **Product Design of the Year** (for the Kit Yamoyo anti-diarrhea kit) - London Design Museum, April 2013
- Top 5% Most Viewed LinkedIn Profiles of 2012
- DFID Grant Recipient for the ColaLife Operational Trial Zambia- USD$ 1.35M, 2012
- **Grand Challenges Canada's Rising Stars in Global Health** Grant Recipient (as PI for the ColaLife Operational Trial Zambia)- CAD$ 100,000, 2012
- Alumni of the **Governor General's Canadian Leadership Conference (GGCLC)** for Top Canadian Leaders in various sectors, June 2012
- Georgeda Buchbinder Research Award, Johns Hopkins School of Public Health, *June 2011*
- Young Alumni Award, Faculty of Applied Health Sciences, University of Waterloo, October 2009
- Featured Alumni Profile, Boston University School of Public Health, *February 2009*
- Celebrating Performance Award, Accenture Health and Life Sciences, *July 2007*
- Profiled as Alumni Success Story for the Faculty of Applied Health Sciences, University of Waterloo, *March 2007*
- Volunteer of the Year, Unite For Sight, *December 2005*
- University of Waterloo John McBain Award for International Entrepreneurship, *2004*
- **Canada Millennium Excellence Award** (National Laureate) – academic achievement, contribution to the community, dedication to leadership and innovation, *2000-2004*
- Vedic Cultural Scholarship - outstanding contribution to the South Asian Community (1st prize), *2000*
- University of British Columbia **Shad Valley** Program Alumnus – international program based on science, entrepreneurship, and technology for top 200 students in Canada, *1999*
- Royal Bank Shad Entrepreneurship Cup – Best Business Plan (CEO of company that invented medical device), *1999*

PROFESSIONAL ACTIVITIES

- Delegate, Canada 150 Social Impact Research and Development (R&D) Retreat, *Wasan Island, July 2015*
- Member of the Global Diarrhea and Pneumonia Working Group, *2014-present*
- Member of the **UN Every Woman, Every Child Innovation Working Group (IWG),** *2010-present*
- Member of the Canadian Association of International Development Professionals (CAIDP), *2013-present*
- Advisory Board Member, Raising the Village, *2012 – present*
- Member of the UN Secretary General's Joint Action Plan for Women's and Children's Health, *2010-present*
- Member of the Canadian Society for International Health, *2009-present*
- Global Fund for AIDS, Tuberculosis and Malaria's Ad-Hoc Committee for the Affordable Medicines Facility – Malaria (AMFm), *June 2008 – April 2009*
- Roll Back Malaria AMFm Task Force, *December 2007 – February 2009*
- Co-Chair (with DFID) of the Roll Back Malaria AMFm Task Force Sub-Group on Reaching the Poor, *June 2008 – November 2008*
- Permanent Secretariat of the CIDA Health Programming Division Results-Based Management (RBM) Committee, *April 2008 – 2010*
- Organizer of the CIDA Health Innovations Series, *July 2008*
- Represented Canada on the Stop TB Coordinating Board, Rio de Janeiro, Brazil, *March 2009*
- Represented Canada at a high level Ministerial Meeting on Tuberculosis Control During the Global Financial Crisis, Rio de Janeiro, Brazil, *March 2009*
- Member of the International AIDS Society (IAS), *2006-2007*

- Member of the Organizing Committee for the AIDS 2006 Conference, Toronto, ON, *August 2006*
- Member of the Delta Omega Public Health Honor Society – Alpha Beta Chapter, *2006 inductee*
- Student Trustee, York Region District School Board, *1999*

SELECTED PRESENTATIONS/CONFERENCES

- Panelist/Speaker, Ubering Global Health: Sustainable Business Models for Healthcare Delivery, **Canadian Conference for Global Health & McGill University**, November 2015
- Keynote Speaker, Public Private Partnerships & Innovation in Global Health, **Dalhousie University,** *April 2015***,** *March 2015*
- Speaker, Revolutionizing Big Pharma for Global Health, **University of Toronto,** *February 2015*
- Guest Lecturer, Social Entrepreneurship & Global Health, **Harvard School of Public Health,** *February 2015*
- Keynote Speaker, Community Partnerships Plenary – **Canadian Conference for Global Health**, *November 2014*
- Invited Panel Moderator for Health and Social Entrepreneurship, Greenhouse, **University of Waterloo**, *October 2014*
- Keynote Public Lecture - **Gates Foundation**, Seattle, United States, *May 2014*
- Invited panelist - Pegasus Conference, Toronto, Canada, *May 2014*
- Invited Presentation - Integrated Community Case Management (**ICCM**) Evidence Review Symposium, Accra, *March 2014*
- Keynote speaker – *Social Innovation*. Center for International Policy Studies, University of Ottawa, *January 2014*
- Invited Presentation and Panelist - *Shifting Behaviours: Tools for Better Health Practices*. **Aga Khan Foundation Canada**, Ottawa, *November 2013*
- Guest Lecturer – *Design and Health*, **Alpert Medical School at Brown University** & **Rhode Island School of Design**, Providence, *December 2013*
- Invited Speaker – *Public, Private Partnerships and Health*. **Stanford University** Graduate School of Business' Center for African Studies and the School of Medicine's Center for Innovation in Global Health, Stanford, *October 2013*
- **UN General Assembly** – high-level private presentation to Prime Minister Stoltenberg of Norway, Princess Sara Zeid, Bill Gates, and PATH CEO Steve Davis, New York, *September 2013*
- Invited Presentation - *Rising Stars in Global Health Symposium*, 53rd Interscience Conference on Antimicrobial Agents and Chemotherapy (**ICAAC**) 2013, an American Society for Microbiology (ASM) meeting, Colorado, *September 2013*
- Invited Speaker – *Revolutionizing Global Health with Cola*, **TEDx Toronto**, *November 2012*. Accessible at: http://tedxtalks.ted.com/video/Revolutionizing-Global-Health-w;search%3Atag%3A%22tedxyouth-toronto%22
- Speaker - 3rd Annual **Global Health Innovation Conference**. "*A Vision of Possibilities: Merging Clinical and Public Health Perspectives in Ocular Health".* Yale University. New Haven, *April, 2006.*
- Speaker - 2nd Annual International Unite for Sight Conference. *"A Successful Model for Comprehensive Eye Care Coverage in the Developing World: The Case of LV Prasad Eye Institute".* Harvard University. Cambridge, *April, 2005.*

SELECTED PUBLICATIONS

- Berry S., Berry J., Ramchandani R. (2015). *Should We Welcome Multinational Companies' Involvement in Programmes to Improve Child Health?* British Medical Journal (BMJ), 350:h3046. Available at: http://www.bmj.com/content/350/bmj.h3046/rapid-responses
- Ramchandani, R. *Impact of Emulating Commercial, Private-Sector Value-Chains on Uptake of ORS and Zinc for Childhood Diarrhea in Rural Zambia: Evaluation of the ColaLife Trial.* (In progress), 2015.
- Ramchandani R. *Product Innovation and Human-Centered Design for Global Health Delivery: Improving Effective Use of Oral Rehydration Salts Through the Introduction of an Innovative Diarrhea Treatment Kit.* (In Progress), 2015.
- Ramchandani R. *Serving the Underserved: A Description of Rural, Commercial General Stores as Community-Level Providers of Public Health Commodities in Zambia.* (In progress), 2015.
- Ramchandani R. Putting the "Live" Back in Delivery. Retrieved December 12, 2014 from: https://www.devex.com/news/putting-the-live-back-in-delivery-84917
- Ramchandani R, Berry S, Berry J. Diarrhea, Seasonality and Climate Change. Retrieved October.30, 2014 from: http://www.colalife.org/2014/10/21/some-thoughts-on-diarrhea-incidence-and-seasonalityclimate-change/
- Ramchandani, R. The Last Word: The Absurdity of Inequity. Waterloo Magazine, Spring 2014. Retrieved from: https://uwaterloo.ca/alumni/sites/ca.alumni/files/uploads/files/c004681_magspring2014_accessible.pdf
- Berry S, Berry J, Ramchandani R. *Top 10 Achievements in 2013.* Retrieved January 14, 2014, from http://www.colalife.org/2013/12/30/top-10-achievements-in-2013/
- Ramchandani R. *Final Survey Kicks Off – Feeling of Slight Relief.* Retrieved January 14, 2014, from http://www.colalife.org/2013/08/22/final-survey-kicks-off-feelings-of-slight-relief/
- Ramchandani R. *Rohit reports on our trip to Katete on 3 December.* Retrieved January 14, 2014, from http://www.colalife.org/2012/12/14/rohit-reports-on-our-trip-to-katete-on-3-december/
- Berry S, Ramchandani R. *Is it right to sell ORS to poor people when they can make their own?* Retrieved January 14, 2014, from http://www.colalife.org/2013/06/15/is-it-right-to-sell-ors-to-poor-people-when-they-could-make-their-own/
- Ramchandani R. *The COTZ Baseline Survey: Part 1.* Retrieved January 14, 2014, from http://www.colalife.org/2012/09/09/the-cotz-baseline-survey-part-1/
- Bishai D, Ramchandani R, Montagu D. Investing in networks as a platform to improve private sector medical care. Bellagio Symposium on Health Markets, December 2012.
- Bennett S, Bloom G, Ramchandani R, Bishai D, Watson N, Kanjilal B, Oladepo D, Peters D. Defining Future Strategic Directions For Development Partners In Health Care Markets: Stakeholder Views & Landscape Analysis. Future Health Systems Consortium, July 2012.
- Ramchandani R, Berry J. Evaluating the ColaLife Operational Trial Zambia: A Journey in Evaluation Innovation. (Summer 2012). EvalNews: UNICEFs Evaluation Newsletter. Accessed on January 14, 2014 from http://www.colalife.org/2012/06/07/evaluating-colalife-operational-trial-zambia-cotz
- Contributor, Private Enterprise for Public Health. Opportunities for Business to Improve Women's and Children's Health. A Short Guide for Companies. Geneva, Switzerland: PMNCH
- Ramchandani R. Innovation in Service Delivery. *Every Woman, Every Child - Investing in Our Common Future: Global Strategy for Women's and Children's Health*. pp.56-61; New York, 2010. Available at: http://www.who.int/pmnch/activities/jointactionplan/100922_2_investing.pdf

SELECTED MEDIA COVERAGE AND EXPERT INTERVIEWS

- Canadian Society for International Health (September 2014). Partnerships for Global Health. Retrieved from: http://www.csih.org/en/blog/canadian-conference-on-global-health-2014/meet-rohit-ramchandani/
- Birnbaum, E. (2014, July 2014) Following in Coca-Cola's Footsteps. **See Change Magazine**. Retrieved from http://www.seechangemagazine.com/article/interviews/744-following-in-coca-colas-footsteps
- Toal, R. Ten of the Most Innovative NGOs in the World. Retrieved from http://www.fundsforngos.org/free-resources-for-ngos/ten-innovative-ngos-world/
- Butschili, J. (2013, July 8) ColaLife Aidpod Kit Package Trial to Conclude in September. **Healthcare Packaging**. Retrieved from http://www.healthcarepackaging.com/applications/healthcare/colalife-aidpod-kit-package-trial-conclude-september
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- Warner, B. (2013, April 8) To Get Medicine to Africa, Health Experts Turn to Coca-Cola. Bloomberg **BusinessWeek**. Retrieved from http://mobile.businessweek.com/articles/2013-04-08/to-get-medicine-to-africa-health-experts-turn-to-coca-cola
- Maly, T. (2013, March 28) ColaLife rides Coke's distribution to deliver essential medicine to remote villages. **Wired**. Retrieved from http://www.wired.co.uk/news/archive/2013-03/28/colalife
- Newsday. November 22, 2012. *Innovative Approaches in Healthcare*. London: **BBC World Service**. Accessed January 14, 2014 from http://www.colalife.org/2012/11/25/colalife-on-the-bbc-world-service-221112/
- Dakin, P (2012, November 22). *Life-saving kits from Zambian children hitch a ride*. **CBC News**. Retrieved from http://www.cbc.ca/m/news/#!/content/1.1219724
- Ward, C. (2012, September 7) Partnering with Coke for the greater good? **MacLeans**. Retrieved from http://www2.macleans.ca/2012/09/07/partnering-with-coke-for-the-greater-good/
- Kilnani R. (2012, May 3) *Coca-Cola Partners in Public Health Initiative.* The Indo-Canadian Report with Rashi Kilnani, **Radio Canada International**. Accessed on January 14, 2014 from http://www.rcinet.ca/english/archives/column/the-indo-canadian-report-with-rashi-khilnani/14-38_2012-05-03-coca-cola-partners-in-public-health-initiative/
- Marshall, A (2012, January-March) A Refreshing Development: In remote, impoverished places where clean water and medicines are hard to find, people can still buy an ice-cold Coke. **Development Asia.**
- Ward, C. (Director). (2012). ***The Cola Road*** [Documentary], New York.
- Godal, T. Klausner, R. (2011). Innovating for Every Woman and Every Child,. Lancet; 379:e1-e2. Retrieved from: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2811%2961393-7/fulltext#article_upsell